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Changing chronic disease primary care patients' participation through web training: Does it make a difference?

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Résumé

Contexte: La communication efficace entre les médecins et les patients peut améliorer les soins. Nous proposons qu'améliorer la participation des patients puisse conduire à une meilleure rétention de l'information au sujet des médicaments et à une atteinte des cibles de soins. **Objectifs:** Chez des patients atteints de maladies chroniques n'ayant pas atteint les cibles de soins, évaluer 1) l'impact d'une intervention *web* encourageant la participation lors de l'entrevue médicale sur l'atteinte de cibles de soins comparativement aux soins usuels (étude A); 2) quelles caractéristiques de communication médecin-patient prédisent la rétention des informations au sujet des médicaments discutés durant la consultation (étude B).

Méthode : Le devis est un essai clinique aléatoire à simple insu. Les patients ont été répartis en trois groupes: a) soins usuels b) formation en ligne (e-*Learning*) c) formation en ligne combinée avec un atelier (e-*Learning* + atelier). Médecins, codeurs et personnel de recherche qui faisait l'extraction des données des dossiers médicaux étaient aveugles par rapport à la répartition. **Contexte:** L'étude s'est déroulée en Ontario dans neuf cliniques de première ligne ambulatoires en milieu urbain entre mars 2009 et septembre 2010. **Population:** Un échantillon de convenance de médecins de famille a été constitué selon les critères d'inclusion suivants : 1) avoir cinq années ou plus d'expérience clinique et 2) desservir une clientèle incluant des adultes atteints de maladies chroniques. Pour être éligibles les patients devaient : 1) être âgés de 40 ans ou plus, 2) parler anglais, 3) être capables d'utiliser un ordinateur pour des tâches simples routinières par exemple, accéder régulièrement à Internet ou au courriel, 4) avoir un suivi prévu 3 à 4 mois suivant la visite initiale d'inclusion, 5) permettre l'accès à leur dossier médical, 6) ne pas atteindre les cibles de soins selon les lignes directrices canadiennes et être traités pharmacologiquement soit pour de l'hypertension, du diabète type II ou de la dyslipidémie. . **Description de l'intervention :** La formation en ligne était basée sur l'approche *PACE* de Cegala (« *Prepare, Ask, Check, Express* »). Les participants au groupe e-*Learning* + atelier bénéficiait d'un atelier interactif additionnel qui visait l'apprentissage expérientiel des mêmes habiletés communicationnelles. **Variables et instruments: Un enregistrement audio** des consultations médicales a été fait. La communication médecin-patient a été analysée à l'aide de MEDICODE et du Système

d'analyse de l'interaction de Roter. Les issues de santé, telle l'atteinte de cibles, ont été évaluées grâce aux valeurs de tension artérielle, d'hémoglobine glyquée et du profil lipidique consignées au dossier médical (étude A). La rétention des patients a été évaluée en comparant les réponses au questionnaire complété immédiatement après la consultation à l'enregistrement audio de la consultation (étude B). **Analyses statistiques:** Une régression de Poisson a servi pour l'analyse de l'atteinte de cibles. Des modèles linéaires mixtes ont été utilisés pour l'évaluation de la rétention.

Résultats: Des patients ayant rencontré les critères d'inclusion (n=322), 221 se sont présentés pour leur visite de suivi. Les participants du groupe e-*Learning* ont atteint plus fréquemment leurs cibles de soins comparativement aux patients du groupe de soins usuels (RR =1.52, 95% CI [1.008-2.30]) (étude A). Pour les analyses de rétention, 159 patients ont été inclus. Sur une possibilité de discussion de six thèmes sur la médication, 2.5 ont été abordés en moyenne et les patients en ont retenu moins d'un. Des discussions abordant plus de thèmes, sous forme de dialogue et initiées plus fréquemment par le patient ont prédit une meilleure rétention de l'information (étude B).

Conclusion: Les résultats des deux études indiquent que la participation active des patients aux consultations médicales a un impact positif sur l'atteinte des cibles de soins et la rétention des informations au sujet des traitements. Des outils en ligne promouvant la participation des patients sont des ajouts importants à la gestion des maladies chroniques.

Mots-clés : soins de première ligne, maladies chroniques, multimorbidité, éducation du patient, Internet, e-Santé, rétention, participation des patients, communication, essais cliniques randomisés

Abstract

Context: Effective communication between physicians and patients can improve health outcomes. We propose that increases in patient participation can lead to better recall of treatment information and reaching treatment goals. Few experimental studies evaluate recall and physiological health outcomes. **Objectives:** To assess, in patients suffering from chronic diseases and not reaching treatment targets, 1) the impact of a web-intervention promoting patient participation on health outcomes as compared to usual care (study A); 2) Assess what characteristics of physician-patient communication predict patient recall of medication information discussed during the encounter (study B).

Methods: This study used a single blind randomized controlled trial. Patients were randomized into three groups: a) usual care, b) web intervention (e-Learning) and c) combined web intervention and workshop (e-Learning + workshop). Physicians, coders and research assistants extracting data from patients' charts were blinded to patient allocation. **Context:** This study was performed in nine urban primary care ambulatory clinics in Ontario between March 2009 and September 2010. **Population:** Physicians were chosen using a convenience sample and the following eligibility criteria: 1) been in practice at least five years and 2) had a practice orientation including adult chronic disease patients. Patients were considered eligible if they met the following criteria: 1) 40 years or more of age 2) ability to speak English, 3) comfortable using a computer for routine activities such as regular access to the web and e-mail, 4) have a routine follow-up visit scheduled within three to four months of study enrollment, 5) allowed access to their medical records, and 6) not meeting Canadian guidelines for treatment targets and pharmacologically treated for at least one of the following three diseases: hypertension, type II diabetes, and/or dyslipidemia. **Study interventions:** The web intervention was based on Cegala's PACE communication approach (Prepare, Ask, Check, Express). Participants in the e-Learning + workshop group benefited from an additional workshop that role-played the same skills. **Variables and instruments:** Medical encounters were audio-recorded. Physician-patient communication was analyzed with MEDICODE and the Roter Interaction Analysis System. Health outcomes, such as meeting target goals on recommended blood pressure, glycated haemoglobin and lipid profiles were

assessed through values extracted from medical records (study A). Patient recall was assessed through answers to a post visit questionnaire completed immediately following the encounter answers compared to audio-recordings (study B). **Statistical analyses:** Reaching treatment goals was analysed with a modified Poisson regression. The analysis of recall was performed with linear mixed models.

Results: Of the patients meeting eligibility requirements (n=322), 221 participants came to their follow up medical visits. Participants in the e-Learning group had a greater likelihood of meeting their treatment goals compared to usual care (RR=1.52, 95% CI [1.008-2.30]) (study A). For recall analyses, 159 patients were included. Out of six possible medication themes two and a half were broached and less than one was recalled. Discussions with more medication themes, greater dialogue and patient initiative were significant predictors of improved information recall (study B).

Conclusion: The results of the two studies provide evidence that patient participation in medical encounters has positive impacts on reaching treatment goals and recall of treatment information. Web-based tools promoting patient participation are important additions in managing chronic disease.

Keywords: primary care, chronic disease, multi-morbidity, patient education, Internet, e-health, recall, patient participation, communication, randomized controlled trials

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List of Acronyms

THT: *Talking Health Together*

PACE: Prepare, Ask, Check, Express

RCT: Randomized Controlled Trial

CD: Chronic Disease

PC: Primary Care

PCP: Primary Care Physician

FP: Family Physician

e-L: e-Learning (web intervention)

e-L + W: e-Learning + workshop (combined intervention)

UC: Usual Care

PCAS: Primary Care Assessment Survey

PACIC: Patient Assessment of Chronic Illness Care

SBP: Systolic blood pressure

DBP: Diastolic blood pressure

HbA1c: Haemoglobin A1c

LDL: Low density lipoprotein

TC/HDL: Ratio of triglycerides over high density lipoprotein

RIAS : Roter Interaction Analysis System

CIM : « Convaincre et éduquer, Implanter, Maintenir »

List of Abbreviations

Etc. : Et cætera

Et al.: and colleagues

This manuscript is dedicated to all of my patients, past, present and future. I will do my best to apply what I have learned from this endeavour to communicate effectively and to advocate for my patients and promote their well being and health.

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Preamble

As a medical clerk, I witness conversations between physicians and patients every day. Often clerks are privy to the aftermath of these conversations: we see physicians, frustrated that patients are not adherent, we see patients who did not quite get what physicians said, or did not receive enough information to complete the task ahead.

As medical students, we have not yet completely entered into the biomedical world of the physician (Mishler, 1984). When physicians say "we're going to try stopping amlodipine", we still have a moment where we say to ourselves "which one was that again?" Often neither the clerk nor the patient dares to ask that question.

In a healthcare context where patients have 10 minutes to spend with their physician, it is reasonable to wonder how we can make the best of that precious time.

When I was introduced to the project of *Talking Health Together* I was immediately intrigued. This project tries to resolve the issue by providing patients with easy and accessible communication tools delivered online. This tool encourages and teaches patients to ask questions, to make sure they are getting the correct information, and to prepare to optimize their encounters.

After working on the primary outcome of this randomized trial, which showed that this tool did in fact change communication between physicians and patients, the practical part of me wanted to know: So what? Does that matter?

When we delve into the health communication literature, we realize that the question of whether effective communication leads to improved outcomes is far from being resolved.

This thesis aims to answer questions regarding whether effective information exchange and patient participation affect outcomes. Specifically, we are interested in discovering if improved physician-patient communication is related to remembering what treatments have been discussed in the encounter. Furthermore, this thesis addresses the question of whether a patient participation tool delivered through the Internet impacts the achievement of treatment goals for particular chronic diseases.

In this thesis we will first provide a brief introduction to health communication. We will explore its relevance and provide conceptual definitions of communication, information exchanges and relationship building. We will examine historical changes in physician-patient relationships. We will examine the advent of the Internet and its role in the dissemination of health information. We are particularly interested in the use of web-based tools in the context of chronic disease, and patient participation within the medical encounter. We will present a conceptual model of how effective communication heals, and provide an overview of current empirical evidence supporting this model.

We will first discuss the methodology of the original *Talking Health Together (*THT*)* trial, and then present two articles, referred to throughout this thesis as study A and study B, focused on health outcomes that were planned secondary outcomes of the trial. Finally, we will discuss the implication of our findings.

Chapter 1: Introduction

1.1 Relevance

1.1.1 Relevance of communication in healthcare

Effective communication between health professionals and patients is inextricable from quality care. For physicians, the majority of their work is achieved through speaking with patients. Studies have shown that taking the history is the overwhelming contributor to making accurate diagnoses (Hampton, Harrison, Mitchell, Prichard, & Seymour, 1975; Silverman, Kurtz, & Draper, 2013). Effective communication is necessary for having conversations about treatments that make sense to patients (Richard & Lussier, 2013), and studies have shown that effective communication can improve medication adherence (Martin & DiMatteo, 2013; Tamblyn et al., 2010; Zolnieerek & DiMatteo, 2009). The importance of communication is recognized in official documents such as CanMEDS 2015 of the Canadian Royal Colleges and Canadian College of Family Physicians, and other international medical institutions (Frank & Danoff, 2007; Neville, 2015; Silverman et al., 2013).

From the patient perspective, research shows that patients value being informed about their diagnoses and treatments (Belcher, Fried, Agostini, & Tinetti, 2006; Braddock, Fihn, Levinson, Jonsen, & Pearlman, 1997; Cox & Butt, 2012; Dickinson D, 2003; Elwyn, Edwards, & Britten, 2003; Goff, Mazor, Meterko, Dodd, & Sabin, 2008; Hudon et al., 2013; Jenkins, Britten, Stevenson, Barber, & Bradley, 2003; Lorimer, Cox, & Langford, 2012; Ziegler, Mosier, Buenaver, & Okuyemi, 2001). In fact, when communication is sub-par patients are dissatisfied. The vast majority of legal action taken against physicians is related to unsatisfactory communication (Kravitz et al., 1996; Lafleur & Chamberland, 2011; Richard & Lussier, 2016; The Canadian Medical Protective Association, 2016). Physicians have a legal and ethical responsibility to communicate and inform their patients effectively (Collège des médecins du Québec, 2010; Gouvernement du Québec, 2016; The Canadian Medical Protective Association, 2016).

Therefore, understanding the role of communication in the context of health care is paramount to achieving effective health care. Research in this topic is necessary in order to guide health care systems, patients and health professionals in their understanding and application of interpersonal communication skills.

1.2 Conceptual Definitions

1.2.1 Communication

According to the Merriam-Webster dictionary ("Merriam-Webster Dictionary," 2017) communication is an " act or instance of transmitting" or an "exchange of information" or a "personal rapport". This broad definition refers to what we will define here as the two major functions of communication: information exchange and relationship building. These two functions can be accomplished through many means, which all fall under the umbrella of different types of communication: verbal and spoken communication, written communication using different modalities such as paper text or through the Internet, and non-verbal communication, including gestures and facial expressions. We focus here on interpersonal communication: the communication between two people (interlocutors). Since non-verbal communication has shown redundancy with verbal communication modes (Labov & Fanshel, 1977), in this thesis we focus on verbal communication.

The concept of interpersonal communication that we elaborate here is inspired from a dialogical approach (Linell, 1998; Richard & Lussier, 2016). This world-view conceives of communication and language not only as a simple means of exchanging information, but rather a creative process: a process of co-constructing realities, finding common ground, and of entering into a relationship with another person (Knapp & Daly, 2002).

Dialogism views communication as a process that is inherently social and collective. Each interlocutor is both a speaker and a listener co-creating content. They also build the relationship between them. The two are engaged in "sense-making" in specific contexts, which happens through this process of interaction.

Inherent to dialogism is the concept of the speech act. Basic instances of language, or utterances, can in fact carry certain actions. For example, if a physician says, "Have you taken

your medications?" this is an utterance. One of the speech acts that we could attribute to this utterance is a question. However, this utterance could also be a challenge, if, for example, the physician doubts the patient's willingness to take their medications. Individuals act upon each other with their speech. Through interactions, they continually define and redefine their relationships, their knowledge, and their understanding of the world.

Dialogism espouses the principles of sequentiality and joint construction. The principle of sequentiality states that each utterance receives its meaning from the previous utterance, as well as from its particular context, as in the example above. The principle of joint construction is the idea that discourse is fundamentally social, interactions are mutually coordinated and there is no part that is single or individual. One can never pre-empt what the next step of a conversation will be and each interaction orients and builds the communicative project. Thus, the dialogical approach is concerned with the context of communication, the interaction and sequence of events, and the content that is built (Linell, 1998; Richard & Lussier, 2016).

As stated above, communication is contextual. The psychological context, the values, attitudes and beliefs of the interlocutors, will inform how they communicate. The relationship between interlocutors also influences communication. The length of their relationship, the level of intimacy, etc. is important in creating the meaning of the interaction. Situational contexts also play a role. Communication in a hair salon is different from that which takes place in a medical encounter. Finally, the socio-cultural context also influences communication (Brown & Fraser, 1979; Labov & Fanshel, 1977; Linell, 1998; C Richard & Lussier, 2016; Tannen, 1984). For example, conversations occurring in the 1950s between Jewish Montrealers were different from conversations occurring now (Federation CJA, 2017).

This dissertation discusses the psychological context, the relationship context and the socio-cultural context as they are manifested in verbal communication within the medical encounter.

Within the healthcare setting, and particularly the medical encounter, there are certain goals of communication that physicians and patients try to achieve. These include increasing the accuracy of the information exchanged, increasing efficiency and building a supportive relationship. Achieving these communication goals is helpful in obtaining the primary goals of

the professional and the patient. Generally, the primary goals of patients and physicians are related to health outcomes: such as healing, and the reduction and prevention of suffering (Richard & Lussier, 2016c; Silverman et al., 2013).

Now that we have defined communication from the dialogical perspective, we will focus specifically on the two functions of communication: the information exchange and relationship building (Richard, Lussier, Galarneau, & Jamoulle, 2016).

1.2.2 Information Exchange

Exchanging of information is a core function of communication especially in the healthcare setting. Information exchange involves information gathering and giving (de Haes & Bensing, 2009). An effective information exchange is one that contributes to the communicative project and aligns the goals of both interlocutors. We can characterize a successful information exchange as one where each of the interlocutors master content and process skills.

Content skills are the substance of discussions, the "what" of the discussion. Professionals, for example, need to determine which questions to ask and which content to share depending on the nature of the problem. Process skills, is the "how" of the discussion. Do we start with "open" or "closed" questions etc.?

An effective information exchange can be seen as one where a certain mutual understanding is achieved. Where the professional and patient understand each other's verbal and non-verbal communication, where there is accurate and efficient data collection, where uncertainty is reduced, and understanding is verified (de Haes & Bensing, 2009; Richard & Lussier, 2016; Silverman et al., 2013).

As stated above, within the dialogical perspective, an information exchange takes place within the relationship and is constantly changing the relationship between the interlocutors. The second core function of communication is relationship building.

1.2.3 Relationship building

In the medical encounter the organizing principle surrounding the relationship between professional and patient is the therapeutic goal. Essential aspects of this therapeutic relationship are trust, respect, rapport and influence (de Haes & Bensing, 2009; Richard & Lussier, 2016; Silverman et al., 2013).

Within the context of the medical encounter, as in most contexts, the relationship is asymmetrical. Barbara Korsch (Korsch, 1974; Korsch & Harding, 1998) defines aspects of this asymmetry in terms of power, knowledge, anxiety and other relational components. Health professionals have a certain expertise about health information that patients do not necessarily have, which is why patients seek out the professional in the first place. However, patients have expertise in terms of their life experiences, or in the voice of the "lifeworld" (Barry, Stevenson, Britten, Barber, & Bradley, 2001; Mishler, 1984). Throughout their communication, each of the interlocutors exerts influence upon the other in order for their world-views to be seen and understood. Thus, as stated above, the relationship influences the information exchange that takes place, and the interactions continually build the relationship.

The nature of this asymmetry has in fact evolved over time, and also changes depending on the particular socio-cultural context that we are in. We will briefly discuss the evolving history and conceptualizations of physician-patient relationships.

1.3 Historical context

1.3.1 Typologies of the physician-patient relationship

Conceptual models of the physician patient relationship have changed historically (Giroux, 2016). Different models, analogies or metaphors have been used to describe these relationships. They often describe differing levels of patient control and involvement.

There has been a transition, in western cultures, from primarily valuing benevolence to putting a greater emphasis on the ideal of autonomy (Taylor, 2009). The rise of individualism and the post-modern, or hyper-modern, focus on the individual has overshadowed the modern focus on social duties and obligations (Lipovetsky, 1983) . These societal trends can be seen in

other relationships, such as the changing role of women, and the fight for individual rights exemplified in the civil rights movement. In the 1950s, social expectation held that patients would respect expert physicians. The differing degrees of patient involvement, elucidated in different physician-patient relation models express the tension between the ethical principles of benevolence and autonomy (Giroux, 2016).

Different typologies have been developed in order to exemplify physician-patient relations. Some typologies use language related to consumerism, autocracy, and autonomy. A common element seen in different typologies of physician-patient relationships is the articulation of power relations between physicians and patients. The typology developed by Emmanuel and Emmanuel (Emanuel, 1992) is widely cited and exemplifies this phenomenon. In this typology the four models of physician-patient relations are: the paternalistic model, the interpretive model, deliberative model and the informative model. The paternalistic model, the dominant model of the post war era, views physicians as guardians. They protect patients' wellbeing, and they know what that is, since it is considered to be objective. The interpretive model views physicians as advisors: interpreting the patient's values, informing the patient and implementing their preferred treatment. The deliberative model views physicians as friends or teachers, articulating and persuading the patient of certain values and implementing the patient's selected interventions. The informative model views physicians as technical experts, providing information and implementing patient's selected interventions (Emanuel, 1992).

In the Emmanuel & Emmanuel typology, patients exert little involvement in the paternalistic model. At the other extreme, in the information model, they are seen as completely autonomous, able to gather information, choose and control their medical care.

Although all of these physician-patient relationships have existed over time, the dominant or preferred model has changed with the historical and societal changes described above. The expectation has evolved to the point where it is currently important to recognize the expertise of both the patient and the physician. They are seen as equals with different perspectives, operating in a partnership (Pomey et al., 2015; Richard & Lussier, 2016b).

1.3.2 Web and Health

One of the societal changes that has influenced the transition toward greater patient autonomy is the democratization and access to knowledge, including information found on the Internet (J. Brown, Noble, Kidd, & Papageorgiou, 2016).

Patients have had recourse to information regarding their health and treatments long before the rise of Internet. In the 1980s, major tensions between the public and the scientific community throughout the AIDS epidemic resulted in exponential media coverage of scientific advances. In the 1990s, medical journalism proliferated and there was a rise in the traditional media coverage of health issues. These changes expressed themselves in a context where individuals were appropriating medical knowledge for themselves. The development of the Internet provided a space that facilitated processes already in motion (Tan & Goonawardene, 2017; Thoër, 2013).

Often compared to the technological revolution of the Gutenberg printing press (Fostier, 2016; Topol, 2015) the Internet offers several advantages. Information is accessible, abundant and generally up to date. It offers the possibility for patients to access information at the exact moment that they need it. Patients' ability to educate themselves at their own pace supports their autonomy in caring for their conditions (Fostier, 2016). A recent study has shown that recourse to health information online does in fact promote active participation within medical encounters (Xiang & Stanley, 2016).

The Internet is indeed accessible. According to the Canadian Internet Registration Authority, in 2013 over 87% of Canadian households access the Internet (The Canadian Internet, 2015). In Québec, this rate reached over 90% in 2016. Furthermore, the age divide in Internet use is decreasing. Seventy-two percent of Quebecers older than 65 have access to the Internet, compared to 90% of Quebecers aged 55-64. This is an 11% increase in access compared to the previous year for the oldest age group.

Quebec households that do not access the Internet are characterized as having significantly lower revenue than those that do. However, this difference is also decreasing over time. Low income households increase their access to the Internet from year to year

glaser Finally, a majority of Canadians and Quebecers use the Internet to search for health related information. Over 60% did so in 2010 (Institut de la statistique du Québec, 2010).

1.4 Healthcare context

1.4.1 Physician-patient relations depending on the context

Not every medical encounter is amenable to providing an active role for patients. In fact, Lussier & Richard argue that there is a repertoire of physician-patient relationships that change according to the context of care (Lussier & Richard, 2008). Furthermore, regardless of context, respect is a fundamental aspect to each of the relational styles. In their view the physician-patient relationship is dynamic-hence there is no "one size fits all" nor "one size fits at all times". They illustrate the possible transformations of this relationship in the figure below (see Figure 1), in which the X axis demonstrates the acuteness of the situation, which ranges from acute to chronic and the Y axis describes the gravity of the situation from serious to minor.

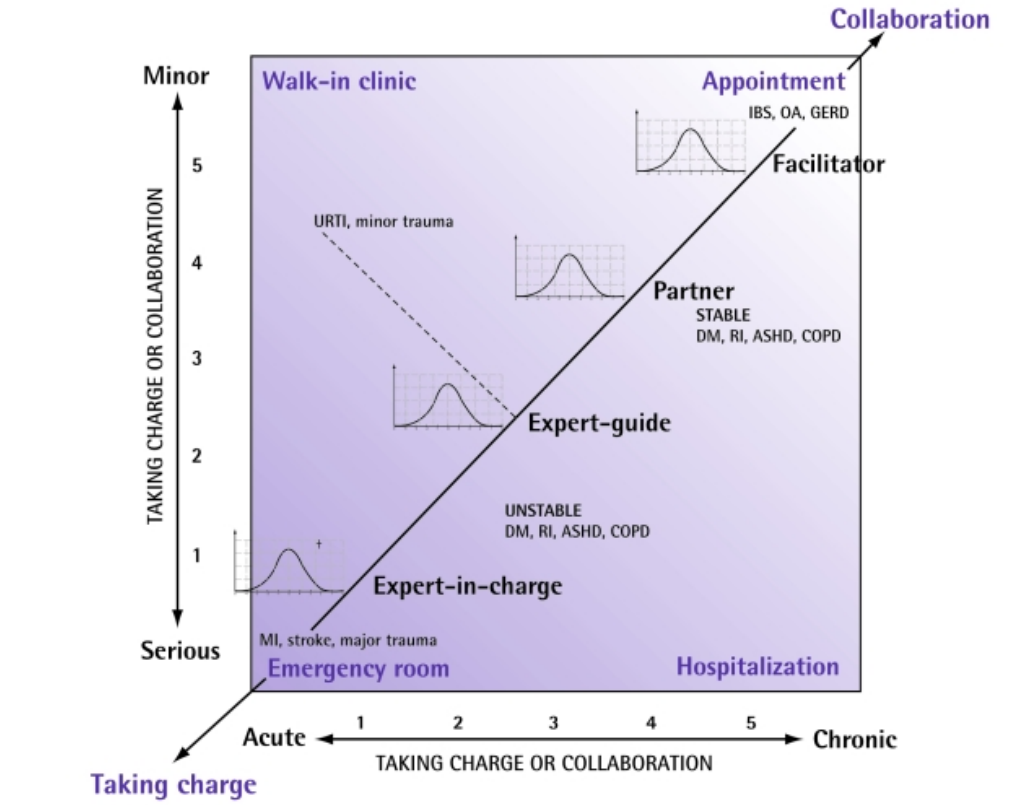

Figure 1. The possible transformations in the physician-patient relationship.

Reprinted with permission from Lussier, M.-T., & Richard, C. (2008). Because one shoe doesn't fit all: A repertoire of doctor-patient relationships. *Canadian Family Physician*, *54*(8), 1089–1092

In a serious acute care situation, septic shock for example, the physician and medical team take charge. This type of relationship is often expected and desired by the patient. However, when health issues are chronic, patients are more apt to take on an active role in their care. Physicians can foster a partnering relationship (Lussier & Richard, 2008). Thus, the physician's role varies from expert-in-charge, to expert-guide, to partner, to facilitator, depending on the context of care. Finally, their model includes a Gaussian curve at each level

showing that there is individual variation within each context. This model speaks to the specific situation of care (emergency room vs ambulatory care). It also takes into account relational and psychological contexts, including age, gender, and culture.

1.4.2 The context of chronic disease

The particular context of care that is addressed in this dissertation is that of chronic illness for which follow-up is provided by a family physician in the ambulatory care setting. This context is situated at the top right corner of the Lussier & Richard model (Figure 1). It is a situation that is chronic and relatively benign. It favours physicians adopting the role of facilitator. It promotes the possibility and necessity of patients taking on an active role in their own health.

Chronic diseases, or non-communicable diseases, according to the WHO, are of "long duration and generally slow progression". They identify four main types: cardiovascular diseases, cancers, respiratory diseases and diabetes (WHO, 2016).

Chronic diseases are the major leading cause of death worldwide. Adults suffering from chronic diseases are frequent users of the health system and generate over two-thirds of health-care related costs (Institut canadien d'information sur la santé, 2014).

Almost half of adults in Quebec suffer from at least one chronic disease and half of those have at least two chronic diseases, or are multi-morbid (Institut de la statistique du Québec., 2016a, 2016b). In fact, prevalence of multi-morbidity depends on the definition used, as well as the context of care (Fortin, Soubhi, Hudon, Bayliss, & van den Akker, 2007; Fortin, Stewart, Poitras, Almirall, & Maddocks, 2012). Prevalence of multi-morbidity is 10% higher in primary care contexts compared to general populations, with estimates ranging from 69.5% to 29.5% in Québecois adults (Fortin, Lapointe, Hudon, & Vanasse, 2005; Fortin et al., 2012; Mokraoui et al., 2016). Furthermore, multi-morbid patients in the primary care context, compared to the general population, have been found to have a higher burden of disease (Mokraoui et al., 2016).

Three chronic diseases in adults that are of particular interest include hypertension, diabetes and dyslipidemia. These three diseases are prevalent and result in significant

morbidity. One fifth of the Québecois population, and up to a quarter of Canadians, are diagnosed with hypertension (Institut de la statistique du Québec., 2016a), 17% of Canadians suffer from dyslipidemia and 10% from diabetes. Hypertension is the most common reason given for a visit to a physician and the number one reason for taking a medication in Canada (Public Health Agency of Canada, 2010). Prevalence of these three diagnoses is increasing over time ("Diabetes in Canada: Facts and figures from a public health perspective," 2011). Hypertension, diabetes and dyslipidemia are optimal chronic diseases in which to study the effect of communication interventions on disease control because they have measurable treatment goals, which we describe in the methods section below. Furthermore, it is important to not that these three diseases are considered concordant, when referring to the typology of Piette & Kerr (Piette & Kerr, 2006). Concordant chronic diseases share an overall pathophysiology and thus in part share similar management plans. Diabetes, hypertension and dyslipidemia are related and affect each other's pathophysiology within the larger umbrella of cardiovascular diseases.

Most patients do not reach their target treatment goals for these three diagnoses despite the availability of treatment (Cheung et al., 2009; Egan, Zhao, & Axon, 2010; Ford, Li, Pearson, Zhao, & Mokdad, 2010). Primary care patients, who are multi-morbid and not reaching targets from these diseases are vulnerable and stand to benefit the most from interventions. Considering the burden of chronic disease in the population and the importance of the optimization of their management, the need for patients to become active and effective participants in their own care is a priority.

1.4.3 The context of the medical encounter: patient participation

Models of chronic disease management argue for the need of "activated" patients. Patient activation is defined as having the knowledge, skills and confidence to manage one's health (Bolen et al., 2014; Greene & Hibbard, 2011; Hibbard, Stockard, Mahoney, & Tusler, 2004). Many studies promote patients' active role in their care through self-management interventions (Bolen et al., 2014; Fletcher et al., 2016; Nuti et al., 2015).

The Chronic Care model highlights the need for patient activation and empowerment, arguing that patients with chronic illness see themselves as their own primary care givers

(Wagner, Austin, & Von Korff, 1996; Wagner et al., 2001, 2005). In the "Montreal Model" the need to see patients as partners is particularly pressing in the context of chronic disease. In this model, patients are seen as partners not only in the clinical encounter, but also in research development, organizational development and teaching (Pomey et al., 2015).

These concepts of patient activation and self-management go beyond the clinical encounter and into the daily lives of patients. The patient journey toward effective self-management is long and challenging. It is punctuated by encounters with health professionals. These encounters may set the stage for the everyday management of one's chronic disease (Richard & Lussier, 2016a).

Thus, a concept related to patient activation is patient participation. Patient participation refers to the patients' communicative behaviours within the medical encounter. Patient participation has been defined as encompassing four components: information seeking (asking questions and checking understanding), frequency of assertive utterances (express an opinion), information provision, and expressing concern (Cegala, 2011; Cegala & Post, 2009; D'Agostino et al., 2017; Haywood, Marshall, & Fitzpatrick, 2006). Systematic reviews of interventions designed to increase patient participation showed that most studies encouraged specific behaviours such as question asking, raising concerns, requesting clarification and checking understanding, however the methods studies use to measure patient participation vary widely (Clayman, Bylund, Chewning, & Makoul, 2016; Harrington, Noble, & Newman, 2004). Examples of interventions that touch on aspects of this definition include question prompt lists (Sansoni, Grootemaat, & Duncan, 2015), the Ask Me 3^{TM} program (National Patient Safety Foundation, 2016) or Cegala's PACE training (Prepare, Ask, Check, Express), which covers all four domains of patient participation (Cegala, Marinelli, & Post, 2000a; Cegala, McClure, Marinelli, & Post, 2000).

Studies have shown that patients who use these communication techniques gain more information from their physicians. Furthermore, when physicians interact with patients who use these techniques they practice a more patient-centered style (Cegala, Post, & McClure, 2001; Cegala, 2011; Cegala & Post, 2009; Post, Cegala, & Miser, 2002).

Patient-centeredness, or the patient-centered clinical method includes four interactive components: 1) Exploring health, disease, and the illness experience, 2) Understanding the whole person, 3) Finding common ground, 4) Enhancing the physician-patient relationship (Stewart et al., 2013). Some of these components echo what we have described above as effective communication. An effective information exchange can be characterized as finding common ground, and enhancing the relationship is the second function of communication. Evidently, patient participation and patient-centeredness are related, the latter promoting the former. However, the patient-centered clinical method is conceived as a method for the physician. In this dissertation we will focus more specifically on patients and their participation in clinical encounters.

While efforts made to improve patient participation and information exchanges in consultations can be seen as valuable goals in and of themselves from an ethical standpoint, the question of whether communication interventions can positively impact health outcomes is an empirical question worthy of exploration.

1.5 Theoretical model

1.5.1 How communication heals?

Street et al.'s model of "How communication heals?" addresses the mechanisms of how improved physician-patient communication may lead to better health outcomes (Street, 2013; Street, Makoul, Arora, & Epstein, 2009). They argue that there is conflicting evidence surrounding communication and health outcomes, with results varying widely depending on which aspects of communication are measured, how they are measured, and which outcomes are being studied. In order to clarify whether communication and outcomes are related they implore the research community to model the pathways through which communication may contribute to outcomes of interest.

In their model, they propose that communication processes can lead to health outcomes directly and/or indirectly. In the direct path communication is healing in and of itself. However, the more likely pathway is through indirect proximal and then intermediate outcomes. Examples of proximal outcomes are constructs such as increased understanding,

increased physician-patient agreement, and increased trust. Examples of intermediate outcomes are patient commitment to treatments, self-care skills, access to care etc. Different health outcomes proposed for study in the model include survival, pain control, and improved control of chronic diseases (Street, 2013).

Using the structure provided in the seminal paper on "How communication heals", it is possible to model a pathway toward improved control of chronic diseases. As described above, we focus here on hypertension, dyslipidemia and diabetes, three diseases with measurable markers for reaching treatment goals: blood pressure, glycated haemoglobin, and lipid profiles.

There are at least two mechanisms that allow for improved control of these diseases: lifestyle modification and medication treatments. Both of these mechanisms depend on the intermediate outcome of adherence. A pathway focused on improved adherence to treatment recommendations posits that more effective information exchanges could improve recall and understanding of treatment recommendations. This may then contribute to improve adherence to treatment recommendations and improve chronic disease control. As previously discussed, increased patient participation may improve information exchanges between patients and physicians. Thus, our specific adaptation of Street et al.'s model is summarized in Figure 2 below:

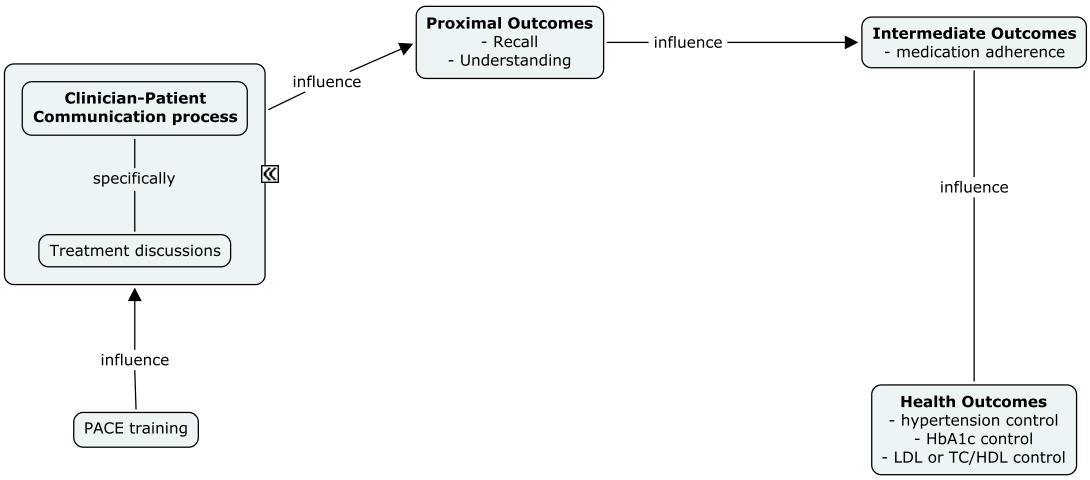

Figure 2. How communication heals: Adapted from Street et al.'s model for a pathway toward improved chronic disease control (Street, 2013)

We will now examine the current evidence for the above-described pathway according to the literature. A literature review was performed to retrieve evidence. This review had specific questions, eligibility criteria, and an identification strategy developed with a librarian. Details can be seen in appendix A.

1.6 Review of the literature

Observational and cross-sectional studies have linked physicians' communication style to certain outcomes such as treatment adherence, satisfaction and recall (Hall, Roter, & Katz, 1988; Martin & DiMatteo, 2013; Zolnieerek & DiMatteo, 2009). Reviews focusing on communication interventions targeted at providers, patients or both, however, have shown mixed and limited results. Interventions are somewhat successful at increasing patient participation, but their effect on proximal outcomes such as recall, and final outcomes, such as physiological measures remains unclear (Auerbach, 2009; Clayman, Bylund, Chewning, & Makoul, 2015; Haywood et al., 2006; Sanders et al., 2013; Schoenthaler, Kalet, Nicholson, & Lipkin, 2014; Shay & Lafata, 2015; Stewart, 1995).

1.6.1 Can we change physician-patient communication processes?

While in the general population there seems to be a belief that being a good communicator is an innate trait of the "good" physician, many authors argue that communication is a series of skills that can be learned (Silverman et al., 2013). Systematic reviews examining the effect of interventions to alter physician-patient communication have shown that these interventions often change communication. Many measures are used, but effects have often been found in perceived and observed patient participation and the number of questions asked by patients (Alders, Smits, Brand, & van Dulmen, 2016; Anderson & Sharpe, 1991; Auerbach, 2009; Clayman et al., 2016; D'Agostino et al., 2017; Galliher et al., 2010; Griffin et al., 2004; Haskard, Williams, Dimatteo, Rosenthal, & Goldstein, 2008; Haywood et al., 2006; Kinnersley et al., 2009; Lewin, Skea, Entwistel, Zwarentein, & Dick, 2001; Mulder, Lokhors, Rutten, 2014; Post et al., 2002; Rao, Anderson, Inui, & Frankel, 2007; Stewart, 1995).

These studies have wide variability. Firstly, some interventions target physicians and others target patients, with a few studies targeting both. Traditionally, interventions to develop communication skills targeted physicians (Post et al., 2002). However, in the past decade studies have turned their focus to training patients.

One of the most studied patient interventions is Cegala's PACE training. This intervention trains patients to prepare for their encounters, ask questions, check their understanding of information and express their concerns. Patients trained through PACE engage in more effective and efficient information seeking. They elicit more information from their physicians. They provide physicians with more detailed information about their medical condition, and use more summarizing utterances to verify information they received from their physicians (Cegala et al., 2001; Cegala, Marinelli, et al., 2000a; McGee & Cegala, 1998).

Another point of variability in intervention studies is the heterogeneity of communication measures. A recent review focused on patient participation described over 24 established measures and a slew of author-created measures for this construct. Some measures are subjective, and based on self-report, while others rely on objective observed communication (Clayman et al., 2016). Despite this variability, there seems to be a general

consensus that interventions aimed at either physicians or patients are effective at changing communication. Whether improved physician-patient communication is related to proximal and intermediate outcomes seems to be less clear.

1.6.2 Patient recall of information

Patient recall of medical information is often poor. Patients forget 40-80% of what has just been discussed; including information related to their diagnoses, risk information related to procedures, and treatment information (Kessels, 2003). A recent study showed that few patients with chronic conditions felt they had clear explanations about side effects and almost all of them were unable to recollect any side effects of their medications (Chan, Wong, So, Kung, & Wong, 2013).

Patient recall of information is defined as the ability to remember what has been discussed in a medical interview (Kessels, 2003; Ley, 1979). This concept can be further broken down into recognition of information and the ability to actively elicit information (Jansen, van Weert, et al., 2008). This conceptual difference impacts measurement. Some authors measure recall using open-ended questions, while others measure recall with multiple choice or recognition-type questions. The type of measurement affects the scores of recall, with open-ended questions generally providing a more dismal view of patient recall of information (Craik & McDowd, 1987). Furthermore, recall is distinct from understanding of information. Patients may remember discussing medical information without having the knowledge of what that information means. In fact, Ley argues that when patients understand information, their recall of what has been discussed is improved (Kessels, 2003; Ley, 1979).

Research shows that recall of medical information is influenced by characteristics that can be grouped into three categories: patient characteristics, information characteristics, and communication characteristics (Kessels, 2003; Ley, 1979). Patient characteristics include age (Jansen, Butow, et al., 2008; Kessels, 2003; Sherlock & Brownie, 2014), education, health literacy (Kessels, 2003; Mccarthy et al., 2013; Ngoh, 2015; Selic, Svab, Repolusk, & Gucek, 2011; Sherlock & Brownie, 2014) and anxiety (Kessels, 2003; Portnoy, 2010; Sep, Van Osch, Van Vliet, Smets, & Bensing, 2014). Information characteristics include modality (written vs aural) (Glicksman, Sherman, & Rotenberg, 2014; Kessels, 2003; Meulen, Jansen, Dulmen,

Bensing, & Weert, 2008; Nicolson, Knapp, Raynor, & Spoor, 2011) structure (Isaacman, Purvis, Gyuro, Anderson, & Smith, 1992; Langewitz et al., 2015; Philip Ley, 1979; McGuire, Morian, Codding, & Smyer, 2000; Werner et al., 2013), number of instructions given (Bravo et al., 2010; Hall et al., 1988; Selic et al., 2011) and encounter length (Jansen, Butow, et al., 2008).

Little is known about which aspects of communication influence recall. Studies have traditionally focused on provider communication (Bartlett et al., 1984; Kessels, 2003). In terms of patient participation, the most often studied behaviour is question asking, and its effect on recall is unclear. Some studies show no effects (Hall et al., 1988; Jansen, Butow, et al., 2008; Sansoni et al., 2015; van Weert, Jansen, Spreeuwenberg, van Dulmen, & Bensing, 2011), others show positive effects (Dillon, 2012) or even negative effects (Hall et al., 1988; Jansen, Butow, et al., 2008; Roter, Hall, & Katz, 1987). Few patient participation interventions assess recall as an outcome of interest. Results are disparate and heterogeneous (Dillon, 2012; Harrington et al., 2004; Post et al., 2002; Sansoni et al., 2015; van Weert et al., 2011). Furthermore, studies measure recall in different ways, and this impacts results. No consistent and validated measure for recall of medical information, or specifically treatment information, has been put forward.

1.6.3 Treatment adherence

That there is a link between recall and treatment adherence has largely been argued from a common sense and theoretical perspective (Kessels, 2003; Ley, 1982; Watson & McKinstry, 2009). Kessels describes Ley's theoretical model where understanding and recall of information predict adherence (Kessels, 2003). These relationships were not empirically tested in the review by Ley (Ley, 1982).

Some empirical studies do show associations between recall of treatment information and medication adherence. Patients with low bone density who better recalled treatment information were more likely to receive prescriptions and to properly take their medications (Pickney & Arnason, 2005). In patients with inflammatory bowel disease, recall of medication information was a predictor of self-reported medication adherence (Linn, van Dijk, Smit, Jansen, & van Weert, 2013). Bartlett and colleagues found an association between recall of

treatment regimens and adherence. Furthermore, in this study recall was highly correlated with physician interpersonal skills, including the exchange of information, and sensitivity to patients' feelings. Physician provision of information and instructions were also related to recall of medication information (Bartlett et al., 1984). Similarly, Schillinger et al., found that assessing recall in patients through the use of "teach-back" was related to better glycemic control in diabetic patients (Schillinger et al., 2003).

These studies demonstrate a relationship between recall and medication adherence, and between communication processes, recall and medication adherence. Unfortunately, these studies are few and limited. More research is needed to clearly link information recall to medication adherence and health outcomes.

1.6.4 Physiological outcomes

Similarly, communication interventions assessing physiological outcomes are scarce. In systematic reviews, randomized controlled trials are the exception rather than the rule. Compared to cross-sectional and observational studies, RCTs show a pattern of null results (Clayman et al., 2016; Shay & Lafata, 2015). Schoenthaler et al., completed a systematic review of the impact of communication interventions on cardiovascular related outcomes (Schoenthaler et al., 2014). This review included 14 trials, 7 targeted at patients. Out of all the trials, only four found significant relationships between interventions and outcomes. The two patient targeted interventions that had an impact include the studies by Greenfield and colleagues that have repeatedly been cited in the literature, despite few replications (Greenfield, Kaplan, & Ware, 1985; Greenfield, Kaplan, Ware, Martin Yano, & Frank, 1988). These studies, along with many others suffer from various methodological issues.

1.6.5 Methodological quality of studies

In Schoenthaler et al., the above-cited review, only 6 of the 14 studies clearly specified their randomization process. Nine of the 14 studies used completer analyses rather than intention to treat analyses. Few studies reported on how they handled missing data. Other issues that are often described in the systematic reviews cited above include: inadequate descriptions of interventions, inadequate descriptions of providers and the patient-provider

relationship, absence of sample size calculations in order to assess type I and type II errors, use of non-objective and non-validated instruments to assess communication, unclear blinding processes, losses to follow up, short follow up periods and lack of theoretical models guiding interventions (Anderson & Sharpe, 1991; Harrington et al., 2004; Kinnersley et al., 2009; Sanders et al., 2013). Furthermore, interventions that target patients often require significant human resources, which limit their application in a "real world" setting.

1.6.6 The place of web technology in behavioural interventions

Previous studies of communication interventions often have the limitation of requiring significant human resources in an already overburdened health system. Considering the wide use of Internet as a means to retrieve information about health, it is not surprising that health care interventions are increasingly being delivered through the web (Griffiths, Lindenmeyer, & Thorogood, 2006).

Web interventions that are designed to offer educational material as well as tools to help patients manage their health are being developed and studied. Studies examining self-management and self-monitoring through web interventions have shown that they improve health outcomes (Kashgary, Alsolaimani, Mosli, & Faraj, 2016; McKoy et al., 2015; Pal et al., 2013; Van Vugt, De Wit, Cleijne, & Snoek, 2013; Zhai, Zhu, Cai, Sun, & Zhao, 2014) and are just as effective as face-to-face or paper interventions (Samoocha, Bruinvels, Elbers, Anema, & van der Beek, 2010; Seo & Niu, 2015). Despite these findings, interventions specifically targeting communication have rarely been delivered through the web. One explanation for this reticence may be that communication has traditionally been seen as a skill that should be learned experientially (Suzanne Kurtz, Silverman, & Draper, 2005) in a face to face communication context.

1.7 Research gaps and objectives

1.7.1 Research gaps

Studies aiming to improve physician-patient communication have rarely shown an impact on physiologically measurable health outcomes. Physiological health outcomes can be

studied in patients with chronic diseases such as type II diabetes, hypertension and dyslipidemia. These diseases are prevalent and responsible for significant morbidity. They also have measurable objective markers for reaching treatment goals. Few communication studies have specifically examined glycated haemoglobin, blood pressure and lipid profiles. Few studies have targeted patients not meeting treatment guidelines for these conditions.

Furthermore, most studies focus on a single disease, restricting their samples to patients with only diabetes, for example. Studies are often executed in specialist settings, which do not accurately reflect the increasing prevalence of multi-morbidity. The primary care context lends itself well to the study of multi-morbid patients, yet few experimental studies are conducted in this setting (Fortin et al., 2005). This remains the case for communication research targeting health outcomes. It is important to focus on patients with concordant multi-morbidity who actively suffer from more than one disease. Furthermore, targeting patients who do not meet guidelines for these conditions allow us to focus on patients with higher disease burden.

Many studies do not use validated coding systems to assess communication. Few communication interventions assess proximal outcomes, such as recall of treatment information (Harrington et al., 2004; Kinnersley et al., 2009). In fact, little is known about which communication variables predict patient recall of treatment information, such as lifestyle and medication discussions. Finally a clear theoretical perspective guiding research is lacking from many physician-patient communication studies.

1.7.2 Dissertation Objectives

This dissertation has two main research objectives responding to the above-cited gaps in the literature.

1. To assess the impact of a PACE inspired web-based communication intervention alone or combined with a workshop, on reaching suggested treatment goals for health outcomes in primary care patients suffering from hypertension, type II diabetes and/or dyslipidemia compared to usual care.

We hypothesize that our two interventions will lead to a greater proportion of patients meeting treatment goals as compared to usual care.

2. To describe recall of lifestyle and medication treatment information and to assess what aspects of physician-patient communication and patient participation predict patient recall of medication information, in off target chronic disease primary care patients.

This dissertation reports on planned secondary outcomes of a randomized controlled trial that was conducted by Lussier and Richard. The primary outcome for the trial was to assess the impact of the PACE interventions on physician-patient communication, and results are reported in Lussier et al. (Lussier, Richard, Glaser, & Roberge, 2016).

Chapter 2: Methodology

2.1 Study design

THT was a prospective randomized trial, where patients were allocated into three groups: a) usual care (UC), b) e-Learning (e-L) or c) e-Learning + workshop (e-L+W). The clinical trial, NCT00879736, was registered with ClinicalTrials.gov and the protocol received ethics approval from the Ontario (Canada) Institutional Review Board using IRB Services, which allowed central ethics approval for all sites. Ethics approval was also received from the "Comité d'éthique de la recherché en santé" (CERES) 16-066-CERES-D of the University of Montreal. Informed consent was obtained from physicians and patients. Physicians were blind to patient study group allocation.

Chapter 2 will describe the original *Talking Health Together (*THT*)* trial design. Three studies have been conducted using data from this trial. The core study focused on the main outcomes of the THT trial: the objective communication between physician and patients and their subjective perceptions of communication. Results have been reported elsewhere (Lussier et al., 2016). The two other studies, related to secondary outcomes of the trial are reported in chapter 3 (study A) and chapter 4 (study B) of this thesis. Study A describes the results related to the impact of the interventions on health outcomes. Study B describes information recall of treatment information discussed during encounters. Details on the methods of these studies are reported in their respective chapters.

2.2 Setting and participants

2.2.1 Setting

This study took place in nine urban and suburban community-based primary care practices in Ontario between March and December 2009. These practices were meant to reflect typical primary care ambulatory practices, outside of university centres.

2.2.2 Participants: physicians

Participating primary care practitioners were chosen using a convenience sample and were considered eligible if they had been in practice at least five years, had a practice orientation toward an adult population, including chronic disease patients, and agreed to the audio-recording of one visit per participating patient.

2.2.3 Participants: patients

Once physicians consented, patients were approached by the study coordinator and enrolled if they consented and met the following criteria: 1) 40 years or more of age, because of higher prevalence of the study conditions in this age group 2) ability to speak English, 3) comfortable using a computer for routine activities such as regular access to the web and e-mail, 4) have a routine follow-up visit scheduled within three to four months of study enrolment, 5) allowed access to their medical records, and 6) being uncontrolled and pharmacologically treated for at least one of the following three medical conditions: hypertension, type II diabetes, and/or dyslipidemia. These conditions were evaluated by their physicians as not meeting treatment targets set by relevant Canadian guidelines at the time of the study (Canadian Diabetes Association Clinical Practice Guidelines Expert Committee, 2003; Khan et al., 2009; McPherson, Frohlich, Fodor, & Genest, 2006). Pregnant patients or those undergoing active cancer treatment were excluded.

2.3 Randomization and procedures

At study enrolment, patients meeting inclusion criteria were randomized to study groups using a central, automated, blocked (R=6) randomization system carried out by the site coordinator. An overview of trial procedures is shown in figure 3.

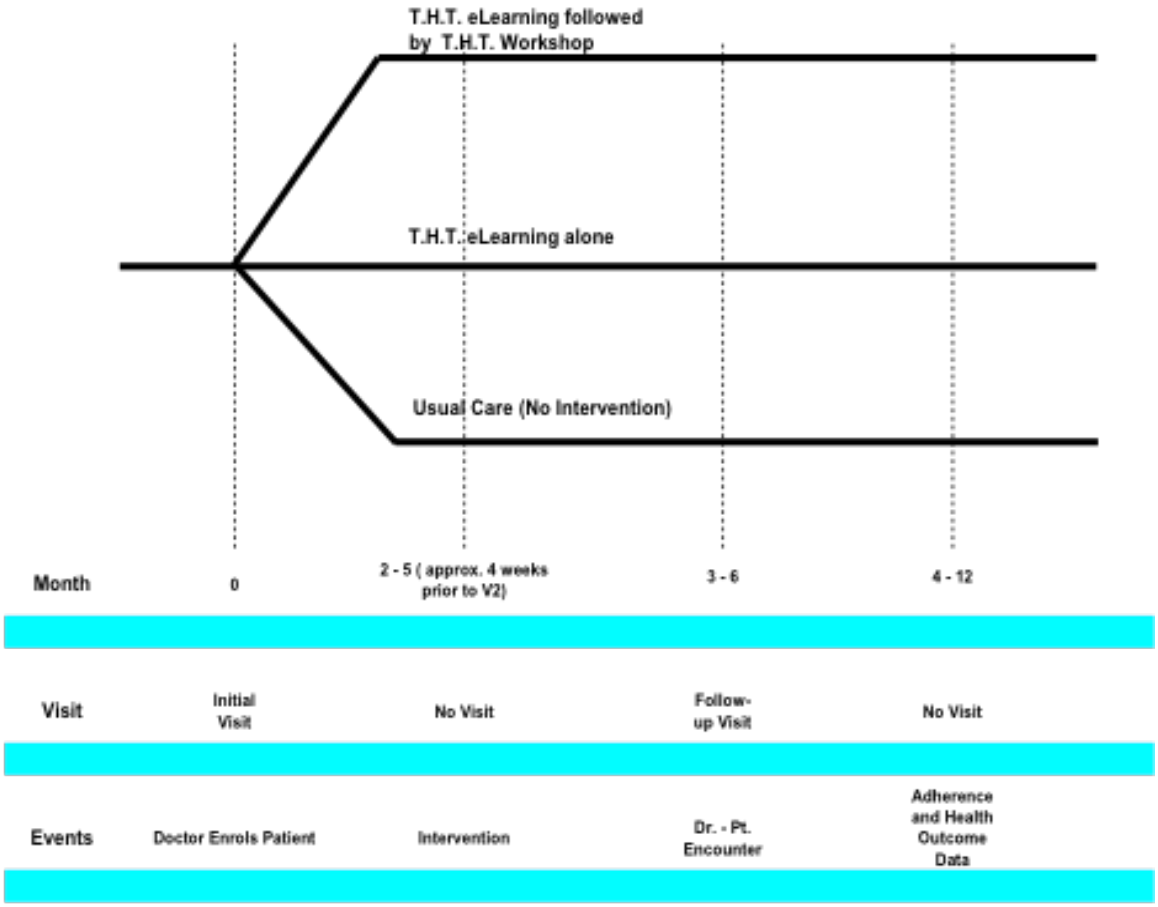

Figure 3. Randomization and procedures of the THT trial

Patients were randomized at the initial visit with their physicians. They had a follow-up visit with their physician in 3-4 months following normal scheduling. Four weeks prior to this visit they were contacted in order to perform the intervention. The follow-up or post-intervention visit was audio-recorded, and patients filled out questionnaires following the encounter. Patient charts were reviewed up to 12 months following this visit. Outcome data for study A was retrieved from these charts. Outcome data for study B was retrieved from the questionnaires at the post-intervention visit.

2.3.1 Patients

Patients completed a baseline questionnaire including socio-demographic data, elements from the Primary Care Assessment Survey (PCAS) (Safran et al., 1998) and the

Patient Assessment of Chronic Illness Care (PACIC) (Glasgow et al., 2005). These questionnaires and related variables are described below.

Patients were scheduled for their follow-up visit within the next three to four months, according to normal office scheduling. The study coordinator instructed patients in the e-Learning and e-Learning + workshop groups on how to access the web intervention using a brochure. Patients were contacted approximately four weeks prior to their scheduled follow-up visit and reminded to access the web. Patients in the e-Learning + workshop group were given instructions on how and when to attend their scheduled workshop. The follow-up visit, which was audio-recorded, is referred to as the *post-intervention visit*.

Immediately following the post-intervention visit, patients completed a questionnaire. This questionnaire included measures for secondary outcomes such as patient's perception of communication, and satisfaction with the encounter. Included in this questionnaire was an assessment of recall of their chronic conditions and treatment information they had just discussed with their physician developed by the research team (results reported in study B). All questionnaires were self-administered.

The last outcome data was retrieved from medical records in September 2010. Patient records were reviewed by a trained research assistant, blind to patient allocation, approximately 12 months after the post-intervention visit for office Systolic Blood Pressure (SBP), Diastolic Blood Pressure (DBP), haemoglobin A1c (HbA1c), and lipid profiles (low density lipoprotein (LDL), and ratio of triglycerides over high density lipoprotein (TC/HDL)) that were charted by the physician before and after the intervention. If more than one value was present, the value closest to the post-intervention visit was chosen. The research assistant also noted any new medications prescribed and/or changes in dosage of medications during follow-up (results reported in study A).

2.3.2 Physicians

At enrolment, primary care physicians completed a basic socio-demographic and practice profile questionnaire. For each participating patient, they completed a post-visit questionnaire at the post intervention visit. They indicated in this questionnaire the condition

for which the patient was enrolled. Physicians also indicated whether they prescribed any medication changes during the visit. They were blind to patient allocation.

2.4 Study Interventions

The PACE communication intervention was delivered either as e-Learning alone or as e-Learning followed by a workshop. These two groups were compared to the usual care group, who had routine chronic disease follow-up visits with their primary care physicians and no additional material.

2.4.1 Development of interventions

The web and workshop interventions were developed in collaboration with an international committee of communication experts including Don Cegala, Angela Coulter, MT Lussier, Claude Richard, and Roger Neighbour. The project was funded by AstraZeneca Canada and they collaborated with the committee of experts to design the website.

Furthermore, a scientific advisory board was established, including Jana Bajcar PhD, Don Cegala PhD, Martin Fortin PhD, Kelly Haskard PhD, Debra Roter PhD, and Richard Street PhD. These experts reviewed the study protocol, and made recommendations regarding the study protocol.

2.4.2 The PACE website

The e-Learning intervention was a web-based, self-directed program that guided patients through each of the four sections of Cegala's PACE approach (Cegala, McClure, et al., 2000; Cegala & Post, 2009). The website presented content in the form of audio, stand-alone text, narrated text and representations of different physician-patient encounters. Patients were able to select and enter information to be printed for their use. The website required approximately 45-75 minutes to complete, and patients could return at their will. The *Prepare* section focused specifically on helping participants organize information to share with their physician, such as their symptoms and which medications they were taking. *Ask* encouraged patients, using examples, to think about questions and write them down, similar to a question

prompt list (Sansoni et al., 2015). *Check* encouraged patients to verify and summarize their understanding. *Express* encouraged patients to voice their concerns.

2.4.3 The PACE workshop

The workshops, which were facilitated by a trained nurse, took place off-site in order to maintain blinding of physicians. Nurses followed a workshop guide and patients were provided with a workshop booklet. The 90-minute workshop encouraged patients to share, interact, and role-play the different PACE communication skills. Patients were instructed to access the e-Learning website prior to the workshop.

2.5 Study Variables

An overview of the variables included in this study is described here (see Table II). For more details on measurement, please refer to chapter 3 and chapter 4 of this thesis. The independent variable for this study was the intervention as described above. THT had a number of dependent variables including observed and perceived communication, treatment information recall, and health outcomes.

2.5.1 Primary outcome: observed communication

The primary outcome for this study was observed communication from audio-recorded encounters. Audio-recorded encounters were analyzed using two validated coding systems: the Roter Interaction Analysis System (RIAS) (Roter & Larson, 2002) and MEDICODE (Richard & Lussier, 2007, 2006a, 2006b). Figure 4 describes the two coding systems.

Roter Interaction Analysis System (RIAS)

RIAS is an interaction based coding system based on social exchange theories (Roter & Hall, 1989). It is inspired by Bale's process analysis system. This system was developed in order to assess patterns of interaction, communication and decision-making in groups. According to this method, how people participate in problem solving can be reflected in the ways in which they communicate. Conceptually, the Bale method views utterances as falling

into one of two categories: socio-emotional or task related (instrumental). Utterances are defined as the smallest speech segment that expresses a complete thought.

RIAS tailors Bale's method to the medical encounter. RIAS assigns one of 42 coding categories to each patient and physician utterance. Utterances are classified as task-oriented (i.e., open and closed questions medical condition, gives information therapeutic regimen, counsels etc.,) or socio-emotional (expression of support, empathy, concern etc.). Outputs that can be aggregated from RIAS include total utterances, frequency of utterance type, proportion of socio-emotional talk to task-oriented talk, and some composite scores. Examples of composite scores include "physician dominance" and "patient control". The former is a ratio of total physician utterances over total patient utterances, where scores > 1 indicate physician dominance. The latter measures the extent a patient leads the talk during the encounter by the number of questions the patient asks and how the physician answers.

RIAS has good psychometric properties. It has been used worldwide in inpatient and outpatient settings. It has good face validity and is one of the few communication measures with a clear theoretical basis. It also has good content and criterion validity (Ong et al., 1998).

Three coders, who were blind to group allocation, received an intensive one-month training in both methods and were supervised on a continuous basis during the coding by two senior coders Claude Richard and Denis Roberge. Inter-rater reliability was calculated on 10% of encounters. Any discrepancies were resolved through group discussion. Average percent agreement for RIAS categories was 90%.

RIAS is a system that focuses primarily on interaction styles. The outputs give aggregates of interactions. RIAS does not capture the dialogical nature of conversation (Sandvik et al., 2002).

MEDICODE

MEDICODE was developed and validated by Richard (Richard & Lussier, 2006; Richard, 2006). At difference with RIAS, MEDICODE focuses on the co-constructing of content between physicians and patients. Content and sequence are incorporated into the coding method. MEDICODE is inspired by a dialogical approach. The methodology most intimately linked to dialogism is conversational analysis (Heritage & Maynard, 2006; Linell,

1998; Maynard & Heritage, 2005; Robinson & Heritage, 2014). MEDICODE shares many qualities with conversational analysis, however responds to a few practical problems noted with the latter. It is a method that is less labour intensive, and can easily provide a more "macro" picture of a conversation. It focuses on certain dimensions of interest established beforehand. It is a quantitative rather than qualitative method. This offers the possibility to perform inferential analyses.

MEDICODE is a content analysis coding system that allows description of communication surrounding medical problems/conditions and treatments within encounters. For each problem and treatment, MEDICODE provides a description of themes broached and their frequencies. It also provides a measure of physician-patient interaction in terms of extent of dialogue and who takes the initiative on each theme discussed (Richard & Lussier, 2007).

Training in this method requires approximately 4 weeks. Coders were trained by a senior coder and were supervised during the duration of the coding, as described above in the RIAS section. Mean Kappa value for MEDICODE was of 0.83, showing good agreement between coders.

Trained coders first identify discussions that physicians and patients engage in during the encounter about medical conditions (see line A in figure 4). For example, when a provider and patient start to discuss "diabetes" this is coded as a problem/condition. If the discussion then moves on to the treatments related to that problem, the coder codes for these treatments. MEDICODE codes lifestyle recommendations, such as diet, exercise, stress management, tobacco and alcohol. MEDICODE also codes for medication treatments. For example, if the physician and patient discuss diabetes and discuss insulin treatment, MEDICODE codes for the medication "insulin" (line B in figure 4). For each treatment discussion identified, coders indicate the themes discussed (line C) in relation to that particular treatment. The coder indicates who initiated the discussion and whether it was a monologue (only one person contributes content to the discussion) or a dialogue (two persons contribute to the discussion).

The themes coded for medications were chosen deductively. These themes were developed with advice from an interdisciplinary committee of experts (pharmacists, geriatrician, anthropologist, psychologist, family physician), patient information guidelines,

and a review of studies dealing with discussions of medications and treatment adherence. The 33 identified themes can be aggregated according to ten major medication-related meta-categories presented in Table I. For example, if a physician starts explaining to the patient how to give insulin injections, this would be coded as "dosage/instructions", physician initiated (and coded as a monologue or dialogue depending on the exchange that ensues).

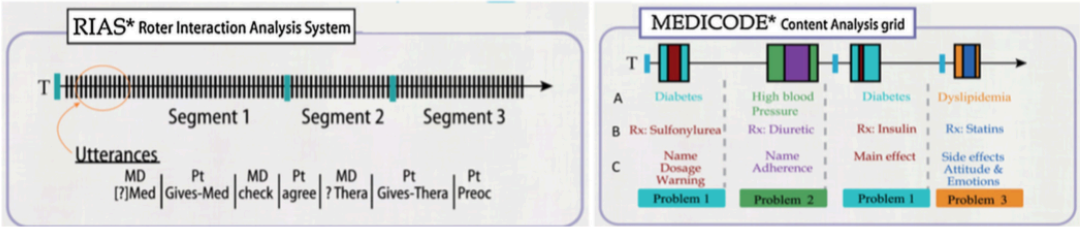

Fig. 1. Brief description of RIAS and MEDICODE coding systems: examples of coding categories and types of coding outputs.
Note:
T = discussions as they unfold during encounter. A succession of utterances in RIAS and a succession of discussions of problems and medications in MEDICODE (many utterances grouped).
A = coding example of three problems in MEDICODE: diabetes, high blood pressure and dyslipidemia.
B = coding example of four medication classes in MEDICODE: sulfonylurea and insulin (diabetes), diuretic (high blood pressure) and statins (dyslipidemia).
C = coding example of specific themes discussed for each medication class identified (Name, Dosage, Adherence, Side effects, Attitudes and emotions, etc.).

RIAS	MEDICODE
Coding strategy: - An interaction-based coding system with some content indicators. - Trained coders attribute a code to each physician and patient utterance. - In this example, MD asks closed question about medical condition; Pt gives information about medical condition; MD checks; Pt agrees; MD asks open question about therapy; Pt gives information about therapy; Pt expresses preoccupation.	Coding strategy: - A content based coding system with some interaction indicators. - Trained coders first identify discussions that physicians and patients engage in during the encounter about medical conditions (line A above) and medications (line B above). - For each medication discussion identified, coders indicate the themes discussed (line C above), who initiated the discussion and whether it was a monologue (only one person contributes to the discussion) or a dialogue (two persons contribute to the discussion).
Examples of coding outputs: - Total and proportion (%) of patient and/or physician utterance counts by coding category. - Composite scores: physician dominance, patient control, PACE score.	Examples of coding outputs: - Total and proportion (%) of medications discussed per encounter. - Total and proportion (%) of themes discussed per medication. - Preponderance of initiative of themes related to each medication discussed. Value of (−1) if theme discussion is patient initiated and (+1) if physician initiated. - Dialogue ratio of themes related to each medication discussed. Value of (0) if it is a monologue and (1) if dialogue.

Figure 4. Brief description of RIAS and MEDICODE coding systems: examples of coding categories and types of coding outputs

Reprinted from Lussier, M. T., Richard, C., Glaser, E., & Roberge, D. (2016). The impact of a primary care e-communication intervention on the participation of chronic disease patients who had not reached guideline suggested treatment goals. *Patient education and counseling*, *99*(4), 530-541, with permission from Elsevier.

Table I. MEDICODE Medication Thematic Meta-categories

Name of meta-category	Short description-*Examples*
Designation	Any reference to medication name, class or description of its format *Glyburide-The blue inhaler-Antihypertensive drug*
Dosage/instructions	Any information related to drug regimen *-Take your cholesterol pill in the evening* *-Take the osteoporosis pill in the morning on an empty stomach*
Adherence	Any information related to the patients adherence behaviour *-How many times did you miss your medication this week?* *-I take my blood pressure pills every morning*
Observed main effect	Discussion of the observed effect of a medication experienced by the patient *- Your blood pressure reading is 120/70. Your blood pressure medications are working.* *- I feel less sad now. The antidepressant is really helping me.*
Expected main effect	Discussion of the anticipated effect of a medication on the patient *- This second blood pressure medication should help us get your pressure under control.*
Observed adverse effect	Discussion of side effects of a medication experienced by the patient *- I really felt dizzy when I took the antibiotic you prescribed for my acne.*

Possible or anticipated adverse effect	Discussion of a potential or predicted side effect of a medication on the patient - *You might feel a bit dizzy at first with this antibiotic*
Contra-indications /Warnings	Discussion of reasons to not take a medication or to be vigilant -*You should not take any alcohol while under this treatment.* -*Because of your allergy to penicillin, we need to give you another type of antibiotic.*
Indication to re-consult	Discussion of reasons for a return visit or getting in touch with the medical team -*If you should experience hypoglycemic attacks after taking the glyburide, you should inform the office nurse.*
Attitudes/emotions towards a medication	Any expression of concern or worry or a positive or negative attitude towards medication -*I don't like taking medications*

2.5.2 Secondary outcome: perceived communication

Patient and physician perception of communication and satisfaction with encounters were secondary outcomes of the trial. Patient perception of communication was measured using existing scales from the PCAS and the PACIC.

The PCAS was developed in order to reflect concepts of primary care. It uses both formal definitions of primary care and concepts from empirical studies. This scale has good internal consistency, item-convergent and item-discriminant validity. Studies have shown good predictive validity for PCAS as well. The PCAS includes the following subscales: longitudinal continuity, visit-based continuity, contextual knowledge of patient, preventive counselling, integration of care, communication, physical examinations, interpersonal treatment, and trust. The sub-scales used included trust, interpersonal treatment and communication. This included items such as: "Doctor's advice and help in making decisions about your care", "doctor's patience with your questions and worries", "I completely trust my doctor's judgements about my medical care".

The PACIC scale was developed as a measure for the Chronic Care Model. It is a 20-item questionnaire measuring five constructs: patient activation, practice design, goal setting, problem solving and follow up. An example from the patient activation scale is: "Asked to talk about any problems with my medicines or their effects." The PACIC scale also has good internal consistency and moderate test-retest reliability after three months. PACIC has good construct validity and concurrent validity when compared to existing patient activation measures. The entire scale was used in the baseline questionnaire.

Details of the primary and secondary outcomes related to communication, including their measurement and findings are reported in Lussier et al. (Lussier et al., 2016).

2.5.3 Secondary outcome: treatment information recall (Study B)

Patient recall of treatment information was assessed by a questionnaire designed specifically for this study. Recall was thus assessed immediately after the encounter. The questionnaire included yes-no questions about whether patients remembered discussing health problems and whether they discussed specific medications and certain themes about the

medications they discussed. Patient responses to the questionnaire were then compared to the coding of medication discussions in MEDICODE. Details about this questionnaire and recall measurement are provided in Chapter 4 for study B.

2.5.4 Secondary outcome: medication adherence

Adherence to medications was a planned dependent variable. Unfortunately, the collection of pharmacy data was not feasible, as a large number of recruited patients were not associated with the RxCanada pharmacy database that the investigators had access to. Since having pharmacy data within a specific pharmacy database was not feasible, this secondary outcome was abandoned.

2.5.5 Secondary outcome: physiological health outcomes (Study A)

Further secondary outcomes of this trial included the following physiologic health outcomes: change in blood pressure, Haemoglobin A1C and lipid profile between pre and post intervention. Measurement of this data is described in Chapter 3.

2.5.6 Covariates

Socio-demographic variables included patients' age, sex, ethnic background, total family income, marital status, and education level. The PCAS subscales used in the baseline questionnaire were longitudinal and visit-based continuity of care. This included questions such as "how long has the physician been your doctor?" or "How many times in the past year have you seen this doctor?"

Table II. Summary Description of Study Outcome Variables

Variable	Instrument/Dimensions studied	Data Source
General variables		
Communication	RIAS 1. Information provision skills 2. Information seeking skills 3. Information verifying skills 4. Expression of concerns 5. Socio-emotional function of encounters 6. Physician dominance 7. Patient control MEDICODE 1.Information exchange on chronic disease (themes) 2.Information exchange on medications (themes) 3.Dialogue ratio 4.Preponderance of Initiative of talk	Audio-recordings of physician-patient encounters
Patient variables		
Perception of physician-patient communication and relationship	Primary Care Assessment Survey (PCAS): (2 subscales) - Communication between patient and provider - Interpersonal treatment domain	Post-Encounter questionnaire
Perception of the management of their chronic disease	Patient Assessment of Care for Chronic Conditions (PACIC): - Patient experience of chronic care management	Post-Encounter questionnaire

Recall of chronic condition, medication and lifestyle recommendations	Patient Recall Questionnaire Patient recall of: - Targeted chronic conditions discussed - Medication and lifestyle recommendations discussed in relation to the targeted chronic conditions	Post-Encounter questionnaire
Patient outcome measures	Patient chart review to collect data before intervention and at 12-month post enrolment for office blood pressure, LDL, total cholesterol/HDL ratio and haemoglobin A1C values	Patient chart review 12 months post enrolment

2.6 Statistical Analyses

I inherited a complete database that included all the relevant data needed to address the questions of the primary outcome and planned secondary objectives. This database included all of the coded communication variables as described above, and data from all the paper questionnaires and chart review.

Baseline characteristics were examined using descriptive statistics, ANOVAs and chi square analyses.

Study A in chapter 3 aimed to examine the impact of the web intervention and the combined intervention compared to usual care on health outcomes. In this study, reaching treatment targets was coded into a dichotomous variable. Thus, analyses were performed using a modified Poisson regression (Zou, 2004) , with usual care being the indicator. Sub-group analyses using linear mixed models were also performed in order to examine mean differences before and after intervention for the various health outcomes. Further details on the analyses performed are presented in chapter 3.

Study B in chapter 4 aimed to examine which communication characteristics predict improved medication information recall. A linear mixed model was performed where

medication was the unit of analysis clustered within patients. The dependent variable was the combined score of recall of medication information, created using results from the comparison of questionnaire responses to MEDICODE coding of medication related information. Variables theoretically related to recall were tested in a multivariate regression. Further details on the analysis of recall are presented in chapter 4.

Power was calculated based on the study's primary outcome of communication (Lussier et al., 2016). Using data from a patient participation hypertension study (Bensing et al., 2006), 100 completed patients per group was estimated to allow for a power of 80%. Statistical power analysis was calculated using behavioural science methodology (Cohen, 1988), assuming a 20% effect size difference between study groups. Statistical analyses were performed with SPSS® version 20.0.

Chapter 3: The Impact of a Patient Web Communication Intervention on Reaching Treatment Suggested Guidelines for Chronic Diseases: a Randomized Controlled Trial

This article was about a planned secondary outcome of the *Talking Health Together* THT trial and is referred to as study A. The article has been published*:* Glaser, E., Richard, C., & Lussier, M. T. (2017). : "The impact of a patient web communication intervention on reaching treatment suggested guidelines for chronic diseases: A randomized controlled trial". *Patient Education and Counseling* (Glaser, Richard, & Lussier, 2017). The article as presented here has some additions not included in the published article. Permission to reproduce the article in its entirety for the purpose of this thesis has been granted by *Patient Education & Counseling* and Elsevier.

The THT trial was conceived of and designed by my two co-authors, MT Lussier and Claude Richard. They developed the protocol, the study interventions and worked to carry out the study.

I inherited a compiled database. Early on, I demonstrated a keen interest in this planned secondary outcome. For this particular study, I updated the literature review. I cleaned and organized the database. The study protocol did not have specificities regarding analyses of health outcomes. I conceptualized these analyses after discussing with my supervisors and with methodological specialists and statisticians. With the help of a statistician, I performed the analyses.

I wrote up the basic draft of the article, including introduction, methods, results and discussion. Dr. Richard, Dr. Lussier and I worked together closely about the discussion of the data. All of us contributed to editing the article. I took the initiative to submit the article to journals. I performed many edits based on reviewer comments from journals. I presented our findings at numerous national and international conferences (E. Glaser, Richard, & Lussier, 2016a, 2016d, 2016e). Reviewer comments and responses for revisions made before publication can be seen in Appendix B.

3.1 Introduction

Chronic diseases (CD) are a major health challenge for primary care in the 21st century (Centers for Disease Control and Prevention, 2014; Elmslie, 2012) and result in significant morbidity, mortality and healthcare costs (Butler, Davis, Johnson, & Gardner, 2011; Cross et al., 2009; Gurwitz et al., 2003; Osterberg & Blaschke, 2005). Some of this burden is preventable through proper disease management. The Chronic Care Model describes a systems-based approach toward improving health outcomes (Wagner et al., 1996; Wagner et al., 2001, 2005) and reducing the care gap between optimal and actual care (Montague, 2005). This model speaks to the importance of productive interactions between health care providers and informed, activated patients.

Patient activation is defined as having the knowledge, skills and confidence to manage one's health (Bolen et al., 2014; Greene & Hibbard, 2011; Greene, Hibbard, Sacks, & Overton, 2013; Hibbard, Mahoney, Stock, & Tusler, 2007; Hibbard et al., 2004). Activated patients show better self-management behaviours (Greene et al., 2013; Hibbard, Greene, Shi, Mittler, & Scanlon, 2015; Hibbard et al., 2007; Remmers et al., 2009). Studies promote patients' active role in their care through self-management interventions (Bolen et al., 2014; Fletcher et al., 2016; Nuti et al., 2015).

Patient activation and self-management as defined above go beyond the clinical encounter and into the daily lives of patients. Communication researchers are interested in patient participation, communication behaviours within the clinical encounter (Cegala, McClure, et al., 2000; Cegala & Post, 2009; Street, 2013). Patient participation within consultations has been defined as encompassing four components: information seeking (asking questions and checking understanding), assertive utterances, information provision, and expressing concern (Cegala, 2011; Cegala & Post, 2009; D'Agostino et al., 2017; Haywood et al., 2006).

Street et al.'s (2009, 2013) model of "how communication heals" posits that clinician-patient communication processes are related to health outcomes, through direct and indirect pathways (Street, 2013; Street et al., 2009). The PACE (Prepare, Ask, Check, Express) training approach (Cegala, Marinelli, et al., 2000; Cegala, McClure, et al., 2000) is one way to

improve physician-patient communication and patient participation (Cegala & Post, 2009; Cegala, Street, & Clinch, 2007; Epstein & Street, 2011). However, limited studies targeting physician-patient communication have examined physiological values such as glycated haemoglobin (HbA1c), systolic and diastolic blood pressure (SBP and DBP), and lipid profiles such as low-density lipoprotein (LDL) and total-cholesterol/high-density lipoprotein (TC/HDL).

Systematic reviews relating to the question of physician-patient communication and health outcomes demonstrate that few studies have a positive impact on these health outcomes (Auerbach, 2009; Clayman et al., 2016; Griffin et al., 2004; Kinnersley et al., 2009; Mulder et al., 2014; Sanders et al., 2013; Schoenthaler et al., 2014; Shay & Lafata, 2015). A recent meta-analysis, performed by Schoenthaler and colleagues (Schoenthaler et al., 2014) examined the impact of communication interventions on cardiovascular risk factors. Fourteen studies were included and only four found positive results. Out of the seven studies targeting patients, only two yielded significant results, one of which belonged to the oft cited studies by Greenfield et al. (Greenfield et al., 1985, 1988). These studies consistently appear as the exceptions in most systematic reviews examining the question of communication and outcomes. The Greenfield studies have particular characteristics that set them aside from most primary care (PC) communication studies. Firstly, their sample was recruited from specialized diabetes clinics. Eighty percent of patients were taking insulin and their baseline HbA1c was above 10%. They showed that a 20 minute intervention promoting patient question asking and information-seeking skills, delivered in the waiting room, decreased HbA1c by 1.53%, an enormous difference considering mean changes in meta-analyses of self-management interventions range between 0.2-0.4% (Bolen et al., 2014; Coulter et al., 2015; Pal, 2013; Zhai et al., 2014).

Like the Greenfield studies, most interventions that aim to train patients on how to communicate within the medical encounter involve coaching by staff or other health care providers and are delivered immediately prior to consultations (Kinnersley et al., 2009; Schoenthaler et al., 2014). Even if these interventions were to prove successful, they may not be feasible in resource scarce health care systems.

Therefore, health care interventions are increasingly being delivered through the web (Griffiths et al., 2006) and studies examining self-management and self-monitoring through

web interventions have shown that they improve health outcomes (Barello et al., 2016; Gee, Greenwood, Paterniti, Ward, & Miller, 2015; McKoy et al., 2015; Pal et al., 2013; Van Vugt et al., 2013; Zhai et al., 2014) and are just as effective as face-to-face or paper interventions (Samoocha et al., 2010; Seo & Niu, 2015). However, interventions delivered through the web are heterogeneous and multidimensional. Determining which aspects of these interventions are responsible for changes in self-management is difficult. Although one crucial aspect of these interventions is the promotion of improved communication between providers and patients (Gee et al., 2015), interventions specifically targeting patient participation have rarely been delivered through the web.

One of the possible critiques regarding this mode of intervention is that they do not provide experiential learning. A solution would be to add workshops to a web intervention (Suzanne Kurtz et al., 2005).

The objective of this paper is to examine the impact of a PACE inspired web-based communication intervention alone or combined with a workshop, on reaching suggested treatment goals for health outcomes in primary care (PC) patients, as compared to usual care. Specifically, we examined patients suffering from hypertension, type II diabetes and/or dyslipidemia who did not meet treatment goals. We hypothesize that our two interventions will lead to a greater proportion of patients meeting treatment goals as compared to usual care. We report here on a planned secondary outcome of the original study, for which the primary outcome was physician-patient communication (Lussier et al., 2016).

3.2 Methods

3.2.1 Study Design

Patients were prospectively randomized using a 1:1:1 allocation into a) usual care (UC), b) e-Learning (e-L) or c) e-Learning + workshop (e-L+W). Because the intervention targeted patients, and not physicians, patients were chosen as the unit of randomization, similar to most patient interventions conducted at the time of protocol elaboration (Greenfield et al., 1988; Harrington et al., 2004; Kidd, Marteau, Robinson, Ukoumunne, & Tydeman, 2004). The clinical trial, NCT00879736, was registered with ClinicalTrials.gov and the protocol received ethics approval from the Ontario (Canada) Institutional Review Board using IRB Services, which allowed central ethics approval for all sites. Informed consent was obtained from physicians and patients.

3.2.2 Setting and Participants

Patients were recruited from nine urban and suburban community-based PC practices in Ontario between March and December 2009, by the study coordinator. The last outcome data was retrieved from medical records in September 2010.

Participating primary care practitioners (PCPs) were chosen using a convenience sample and were considered eligible if they had been in practice at least five years, had a practice orientation toward an adult population, including chronic disease patients, and agreed to the audio-recording of one visit per participating patient. Once physicians consented patients were approached by the study coordinator and enrolled if they consented and met the following inclusion criteria: 1) 40 years or more of age, because of higher prevalence of the study conditions in this age group and because the website content and format was geared to this age-group, 2) ability to speak English, 3) comfortable using a computer for routine activities such as regular access to the web and e-mail, 4) have a routine follow-up visit scheduled within three to four months of study enrollment, 5) allowed access to their medical records, and 6) not meeting treatment targets for at least one of the following three diseases: hypertension, type II diabetes, and/or dyslipidemia, as determined by their physicians according to Canadian guidelines (Canadian Diabetes Association Clinical Practice Guidelines

Expert Committee, 2003; Khan et al., 2009; McPherson et al., 2006) and 7) receiving a prescribed medication for the chronic disease for which they were included. Pregnant patients or those undergoing active cancer treatment were excluded.

3.2.3 Procedures and Randomization

At study enrollment, patients meeting inclusion criteria were randomized to study groups using a central, automated, blocked (R=6) randomization system and carried out by the site coordinator. Patients completed a baseline questionnaire including socio-demographic and clinical data using the Primary Care Assessment Survey (Safran et al., 1998) as well as questions pertaining to patient morbidity. Physicians completed a basic socio-demographic and practice profile questionnaire. For each participating patient at each visit, physicians completed a post-visit questionnaire. They indicated the disease for which the patient was enrolled. Physicians also indicated whether they prescribed any medication changes during the visit. They were blind to patient allocation. At enrollment, patients were scheduled for their follow-up visit within the next three to four months, according to normal office scheduling. The study coordinator instructed patients on how to access the web intervention using a brochure. Patients were contacted by telephone approximately four weeks prior to their follow-up visit and reminded to access the web, as well as given instructions on how and when to attend their scheduled workshop, if pertinent. The follow-up visit was audio-recorded and will be referred to in this paper as the *post-intervention visit*. Patient records were reviewed by a trained research assistant, blind to patient allocation, approximately 12 months after the post-intervention visit for office SBP, DBP, HbA1c, and lipid profiles (LDL, and TC/HDL) that were charted by the physician before and after the intervention. If more than one value was present, the value closest to the post-intervention visit was chosen. Furthermore, assistants noted a number of comorbid diagnoses from patient charts, inspired by the burden of illness subscale of the PCAS (Safran et al., 1998).

3.2.4 Study Interventions

The communication interventions were delivered as 1) e-L or 2) e-L +W. These were compared to a UC group, who had routine chronic disease follow-up visits with their PCPs and no additional material.

Both interventions were designed and content validated by a scientific advisory board, including the PACE intervention developer, Don Cegala, who ensured the website remained true to his program and approved final versions. The website was informally pilot tested with adult users.

The e-Learning intervention was a self-directed program that guided patients through each of the four sections of the PACE approach (Cegala, McClure, et al., 2000; Cegala & Post, 2009), requiring an average of 45-75 minutes to complete. This could be done in more than one sitting at the patients' leisure. Patients were able to select and enter information to be printed for their use. The website presented content in the form of audio, stand-alone text, narrated text and representations of different doctor-patient encounters. The *Prepare* section focused specifically on helping participants organize information to share with their physician, such as their symptoms and which medications they were taking. *Ask* encouraged patients, using examples, to think about questions and write them down, similar to a question prompt list (Sansoni et al., 2015). *Check* encouraged patients to verify and summarize their understanding. *Express* encouraged patients to voice their concerns.

The workshops, which were nurse facilitated, took place off-site in order to maintain blinding of physicians. Patients were instructed to access the e-Learning website prior to the workshop. The 90-minute workshop encouraged patients to share, interact, and role-play.

3.2.5 Outcome variables

The outcome of interest of this paper is the proportion of patients meeting treatment suggested guidelines. Physiologic outcomes were coded as on-target in accordance with guidelines in effect at the time (Canadian Diabetes Association Clinical Practice Guidelines Expert Committee, 2003; Khan et al., 2009; McPherson et al., 2006). These targets are presented in Table 1. Patients were considered off target if their DBP or SBP was >90mm Hg

or >140 mmHg respectively and >80mmHg or >130mmHg for diabetics. Diabetes was considered off target if HbA1c was greater than 7.0%. Lipids were off target if LDL ≥5.0 mmol/L or TC/HDL ≥6 mmol/L in low risk patients. LDL ≥2 mmol/L or TC/HDL ≥4 mmol/L was off-target in high risk patients.

Framingham risk scores were not available, thus patients were considered high risk if they had either a diagnosis of diabetes, a previous myocardial infarction, congestive heart failure, angina, ischemic heart disease or coronary artery disease, as noted in the chart review. Because of the multi-morbid nature of our patient sample, a combined on-target score was calculated, whereby patients were considered on-target if they met treatment guidelines for all of the study diseases they were enrolled for. For example, a patient enrolled for hypertension and diabetes that had controlled hypertension, but an HbA1c> 7.0%, was considered off-target.

Sub-group analyses were performed to examine mean values for SBP and DBP for patients enrolled for hypertension, HbA1c for patients enrolled for diabetes, LDL and TC/HDL for patients enrolled for dyslipidemia.

3.2.6 Statistical Analyses

Analyses were performed only on patients who came to their post-intervention visit (n=221; UC=83; e-L=80; e-L+W=58), with the exception of "worst" case sensitivity analysis described below. Baseline characteristics of groups were analyzed using Chi square tests and ANOVAs. A modified Poisson regression (Zou, 2004) was performed to assess the effect of study groups, with usual care being the indicator, on the proportion of patients meeting treatment guidelines post-intervention. Covariates measured at baseline are presented, however were not inserted into the model, in order to mitigate type I error (Friedman, Furberg, & DeMets, 2010). Patients were included in these analyses despite the fact that they may not have properly completed the web or the combined workshop, following intention to treat principles. A sensitivity analysis was conducted to determine "intermediate" and "worst" case scenarios. In the "intermediate" case scenario, data missing from records of patients who came to their post-intervention visit was coded as off-target. In the "worst" case scenario, following

an intention-to-treat like analysis, all data that was missing, including all the data from patients who were lost to follow up, was considered off-target.

Because of the relevance of presenting mean-values, sub-group analyses were performed for patients who came to their post-intervention visit and were enrolled as off-target for a particular diagnosis (hypertension (n=133), diabetes (n=86), dyslipidemia (n=88). Linear mixed models were used to compare the effect of treatment group on means for SBP, DBP, HbA1c, LDL and TC/HDL.

All tests used an alpha level of 0.05 and confidence intervals of 95%, where applicable. Power was calculated based on the study's primary outcome of communication. Changes in physician-patient communication were not tested in this paper and are reported in Lussier et al. (Lussier et al., 2016). Using data from a patient participation hypertension study (Bensing et al., 2006), 100 completed patients per group was estimated to allow for a power of 80%. Statistical power analysis was calculated using behavioural science methodology (Cohen, 1988), assuming a 20% effect size difference between study groups. Statistical analyses were performed with SPSS® version 20.0.

3.3. Results

3.3.1 Physician description

The 18 participating PCPs were on average 51.2 (*SD*=6.85) years old, predominantly male (14/18) and in practice for a mean of 25.2 (7.02) years (min/max: 15–39). A majority of these physicians worked in group practices (11/18) and saw a mean 4.5 (*SD*=1.3) patients per hour (min-max: 2.5–8.0). Each physician contributed an average of 12.4 (*SD*=7.1) patients to the study (min-max: 1–23). Physicians indicated no change to medication regimens in over 70% of off-target cases, with no differences between study groups $\chi^2(2, N=221)=1.863$, p=0.39.

3.3.2 Patient description

Figure 5 shows the CONSORT randomization process and patient flow. Table III shows baseline socio-demographic and clinical characteristics by study group. No significant differences were found between groups for variables shown in Table III. Most participants knew their physicians longer than five years, had more than four annual visits, and had a high school education. Table IV describes the characteristics of the sample in relation to multi-morbidity. Two thirds of the patient sample had more than one chronic disease. More than half of the sample had disconcordant diseases, meaning they had at least one cardiovascular related disease (hypertension, diabetes, dyslipidemia, angina/CAD, chronic heart failure) and other unrelated diseases (such as depression, arthritis). Less than a fourth of patients met treatment guidelines at study enrolment.

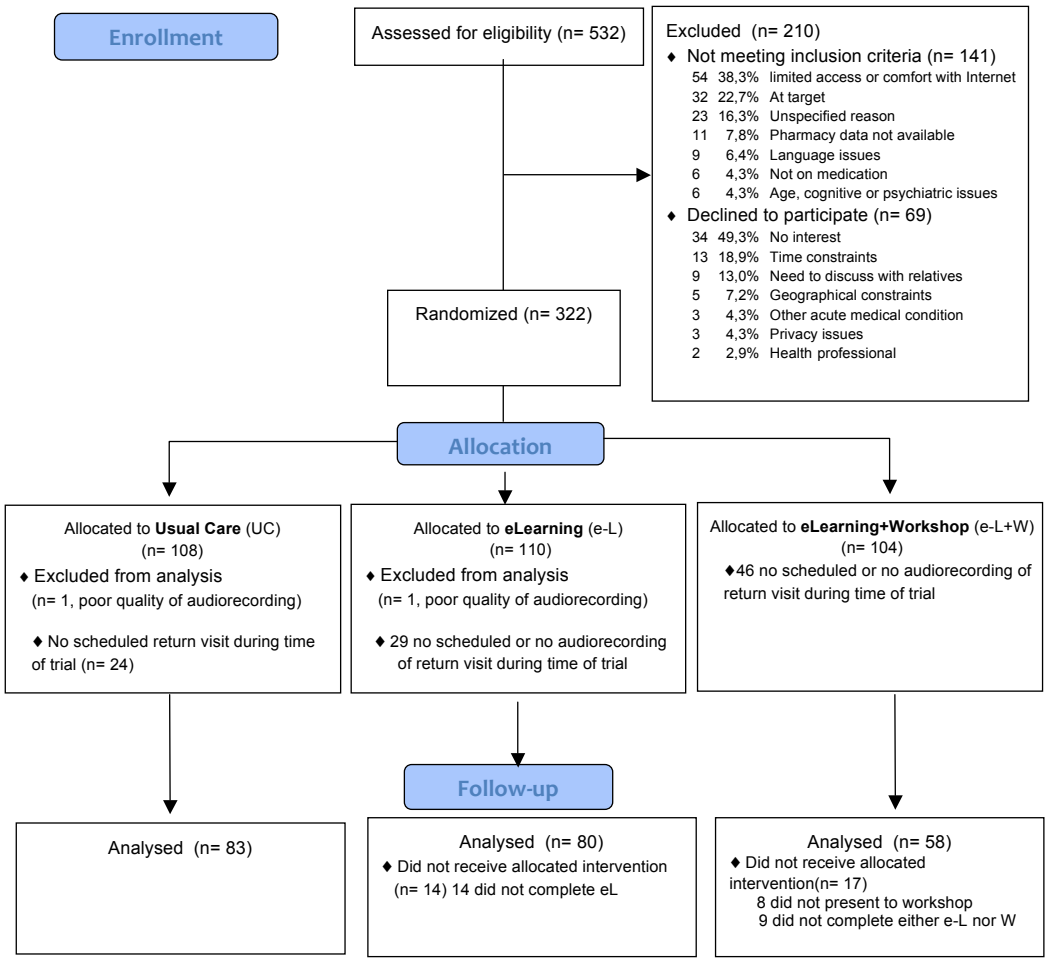

Figure 5. CONSORT Patient flow diagram

Table III. Baseline socio-demographic and clinical characteristics (n=221)

	UC n=83	e-L n=80	e-L+W n=58
Age – mean (SD)	58.1(10)	57.0(8)	60.0(10)
Male sex no. (%)	49 (59)	50 (63)	30 (52)
High school completed no. (%)	61 (74)	58(73)	40(69)
Income $ (CAD) no. (%)			
<20 000	6 (8)	11 (15)	8 (16)
20 000- 39 000	14 (19)	17 (23)	8 (16)
40 000 – 59 999	17 (23)	8 (11)	7 (14)
60 000 – 79 999	9 (12)	15 (20)	13 (26)
> 80 000	29 (39)	23 (31)	15 (29)
Ethnicity			
White no. (%)	61 (74)	63 (79)	41(71)
Black no. (%)	5 (6)	3 (4)	4 (7)
Asian no. (%)	8 (10)	8 (10)	10 (17)
Other no. (%)	8 (10)	6 (8)	3 (5)
Relationship with PCP			
More than four visits in past year no. (%)	60(72)	49(61)	40 (69)
Length of relationship with PCP >5 years no. (%)	60(72)	57(71)	43(74)
Study Chronic Diseases no. (%)			
Hypertension	48(59)	51(64)	34(60)
Diabetes	33(40)	27(34)	26(46)
Dyslipidemia	32(39)	35(44)	21(37)
Proportion on-target no. (%)*	16(23)	16(22)	13(25)

Note. e-L = e-Learning. e-L+W= e-Learning + workshop. UC=Usual Care. PCP=primary care practitioner, CD=chronic disease, DBP=diastolic blood pressure, SBP=systolic blood pressure.
*Patients are considered on-target if they were on-target for each of the diseases they were enrolled for, according to Canadian guidelines of 2008, using the following criteria as off-target:

Hypertension	DBP >90 mmHg or SBP>140mmHg DBP>80mmHg or SBP>130 mmHg in diabetics
Diabetes	HbA1c>7.0
Dyslipidemia	Low Risk: LDL ≥5.0 mmol/L or TC/HDL ≥6 mmol/L High Risk: LDL ≥2 mmol/L or TC/HDL ≥4 mmol/L

Table IV. Concordant and multi-morbidity by study group (n=221)

	UC n=83	e-L n=80	e-L+W n=58
Other Chronic diseases, no. (%)*			
Congestive heart failure	1(1)	3(4)	4(7)
Angina/CAD	12(14)	4(5)	12(21)
History of Cancer	1(1)	5(6)	6(10)
Migraines	6(7)	3(4)	2(3)
Arthritis	11(13)	14(18)	14(24)
Chronic back pain	17(20)	14(18)	14(24)
Asthma, emphysema, lung problem	15(18)	15(19)	8(14)
Liver trouble	1(1)	4(5)	1(2)
Insomnia	5(6)	3(4)	7(12)
Chronic heart burn/ulcers	15(18)	12(15)	9(15)
Depression	16(19)	11(14)	8(14)
Disconcordant CD, no. (%)[a]			
1 CD	32(39)	38(48)	25(43)
2 CD	28(34)	17(21)	16(28)
3 CD	11(13)	18(23)	10(17)
4 CD	9(11)	3(4)	2(3)
5 CD	1(1)	0(0)	0(0)
6 CD	2(2)	1(1)	2(3)
7 CD	0(0)	1(1)	1(2)
Total number of CD, no. (%)[b]			
1 CD	22(27)	24(30)	19(33)
2 CD	26(31)	17(21)	13(22)
3 CD	13(16)	23(29)	7 (12)
4 CD	10 (12)	11(14)	7(12)
5 CD	8(10)	2(3)	6(10)
6 CD	1(1)	2(3)	1(2)
7 CD	2(2)	0(0)	3(5)
8 CD	0(0)	1(1)	1(2)

Note. e-L = e-Learning. e-L+W= e-Learning + workshop. UC=Usual Care. PCP=primary care practitioner, CD=chronic disease. CAD= coronary artery disease.
* Chronic diseases that participants had other than the three main study diseases (hypertension, diabetes and dyslipidemia). Data was gathered from the chart review.

[a] Hypertension, diabetes, dyslipidemia, chronic heart failure & angina/CAD were considered concordant diseases. Patients with disconcordant diseases had at least one of the concordant diseases and at least one of the other chronic diseases listed above.
[b] The total number of chronic diseases that participants had, including the three main study chronic diseases (hypertension, diabetes, dyslipidemia) and the list of other chronic diseases.

Table V. Differences on socio-demographic characteristics between losses to follow up and completers

	Loss to follow up (n=99)	Completers (n=221)	χ^2	p-value
Physician male no.(%)	89 (88)	174 (79)	4.3	0.043
			4.3	0.038
Ethnicity				
White no. (%)	63 (64)	165(75)		
Black no. (%)	9 (9)	12 (6)		
Asian no. (%)	22 (22)	26 (12)		
Other no. (%)	5 (5)	17 (8)		
			12.2	0.002
Study Group				
UC no. (%)	25 (25)	83 (38)		
e-L no. (%)	30 (30)	80 (36)		
e-L + W no. (%)	46 (46)	58 (26)		

Note. e-L = e-Learning. e-L+W= e-Learning + workshop. UC=Usual Care.

Of the 322 patients randomized, 99 patients did not return for their follow-up appointment in the allotted time, despite multiple reminders from study coordinators. These patients were similar to the remaining sample on most socio-demographic or clinical characteristics including age, gender, education, income, CD profile, length of relationship with physician, and number of visits to their PCP in the preceding year. However, three differences are of note, see Table V: patients lost to follow-up were more often of Asian descent, more likely to be followed by a male physician, and randomized to the workshop group. Of the patients randomized to the e-L+W group, 46 did not return for follow up. Three of these patients accessed the website and none went to the workshop. Of the patients randomized to the e-L group, 30 were lost to follow-up and three accessed the website.

Patients accessed the website on average 22 (*SD*=31.6) days prior to the post-intervention visit (min:0; max: 178). Of the 115 patients who accessed the website, 99 visited all four sections of the website. Metrics were not collected on time spent on the website. Workshops were given in groups of 2-3 participants. They occurred on average 27 (*SD*=27.7) days prior to the post-intervention visit (min: 2; max: 136).

3.3.3 Proportion of patients meeting treatment suggested guidelines post-intervention

Pre-enrolment values for BP, HbA1c, LDL and TC/HDL were recorded on average (SD), respectively 19.3 (47.8); 37.4 (49.0); 47.6 (65.5) and 46.9 (63.7) days before enrolment. Post-intervention values were recorded on average 149.6 (78.8); 122.7 (74.0); 136.3 (86.8); and 132.2 (87.9) days after the audio-recorded visit.

Figure 6 shows the proportion of patients meeting treatment guidelines pre and post-intervention. Approximately 20% of patients were on-target for all three study groups before the intervention. Post-intervention, more than half of the e-L group reached targets compared to a third of those in usual care and 43% in the combined e-L+W group.

Table VI reports risk ratios for each of the intervention groups as compared to usual care post-intervention. Analyses were performed using only the data that was abstracted from medical records after follow-up. The e-Learning group had a higher likelihood of reaching target compared to usual care. The combined group was not significantly different from usual care. An "intermediate" case analysis was performed to minimize the effect of missing data. Missing data in the 221 patients was coded as off-target. These analyses showed a similar increased likelihood of e-Learning reaching target compared to usual care. Finally, a "worst" case scenario, coded all missing data, including losses to follow-up as off-target (n=322). These analyses showed the previous findings to be robust, with a trend towards statistical difference.

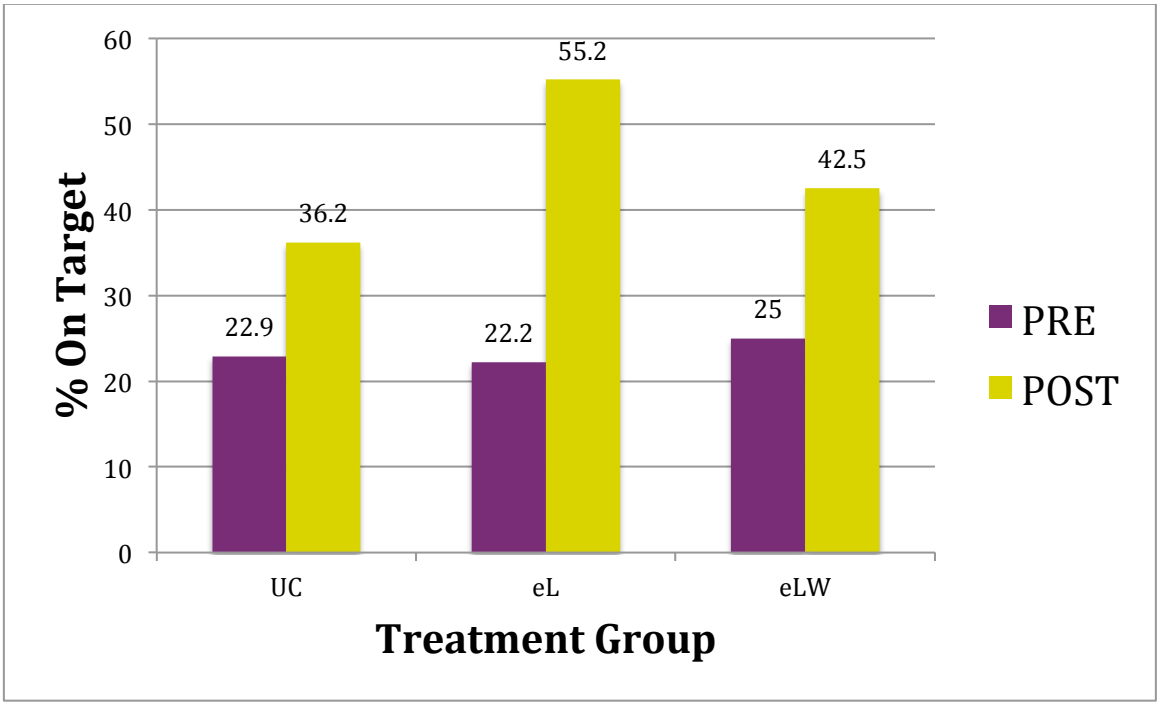

Figure 6. Percent of patients by study group meeting target guidelines for all the diseases they were enrolled for (hypertension, diabetes, dyslipidemia) pre and post intervention.

Note. UC=usual care; e-L=E-Learning; eL+W=e-Learning + workshop; DBP=diastolic blood pressure; SBP=systolic blood pressure

Patients are considered on-target if they were on-target for each of the diseases they were enrolled for, according to Canadian guidelines of 2008, using the following criteria as off-target:

Hypertension	DBP >90 mmHg or SBP>140mmHg DBP>80mmHg or SBP>130 mmHg in diabetics
Diabetes	HbA1c>7.0
Dyslipidemia	Low Risk: LDL ≥5.0 mmol/L or TC/HDL ≥6 mmol/L High Risk: LDL ≥2 mmol/L or TC/HDL ≥4 mmol/L

Table VI. Impact of study interventions on the proportion of patients meeting treatment guidelines compared to usual care.

	No. (%)*	RR (95% CI)	P-value
Original Analysis (n=158) †			
UC (n=59)**	21 (35.6)	--	--
e-L (n=59)	32 (54.2)	1.42 (1.00-2.00)	0.045
e-L +W (n=40)	17 (42.5)	1.11 (0.80-1.54)	0.54
Intermediate Analysis (n=221) ‡			
UC (n=83)*	21 (25.3)	--	--
e-L (n=80)	32 (40.0)	1.24 (1.00-1.55)	0.049
e-L +W (n=58)	17 (29.3)	1.05 (0.86-1.3)	0.60
Worst-case Analysis (n=322) §			
UC (n=108)*	21 (19.4)	--	--
e-L (n=110)	32 (29.1)	1.14 (0.98-1.32)	0.099
e-L +W (n=104)	17 (16.3)	0.96 (0.85-1.09)	0.56

Note. e-L = e-Learning. e-L+W= e-Learning + workshop. UC=Usual Care.
*Number and percentage of patients on-target post-intervention for all of the diseases for which they were enrolled as uncontrolled.
**Usual care was used as the indicator for risk-ratios.
† Only available data from medical records.
‡ Intermediate sensitivity analysis coding missing data for those attending their post-intervention visit as off-target.
§ Worst-case sensitivity analysis coding missing data, including losses to follow up, as off-target.

3.3.4 Sub-group analyses: Physiologic data means by disease enrolment (n=133, hypertension; n=86, diabetes; n=88, dyslipidemia)

Descriptive statistics of means pre & post-intervention for SBP, DBP, HbA1c, LDL & TC/HDL can be seen in Table VII.

Linear mixed models were used to test the effect of study group on the following dependent variables: mean SBP, DBP, HbA1c, LDL &TC/HDL, pre and post-intervention. For SBP, there was no significant effect of study group, nor a group*time interaction, yet there was a significant effect of time, $F(1,117.6)=16.85$, $p<0.001$ 001 indicating lowering of SBP measurements. Diastolic blood pressure showed no effect of time, group, nor an interaction.

HbA1c only showed a marginal effect of time $F(1,46.25)=3.67$, $p=0.062$. Similarly, LDL, $F(1,34.21)=12.22$, $p=0.001$, and TC/HDL, $F(1,46.67)=14.6$, $p<0.001$, values only showed an effect of time.

Table VII. Baseline and post-intervention means for systolic blood pressure (SBP), diastolic blood pressure (DBP), glycated haemoglobin (HbA1c), low-density lipoprotein (LDL) and total-cholesterol/high-density lipoprotein (TC/HDL) for subgroups of patients enrolled.

a. Mean Systolic blood pressure, mmHg (n enrolled=133)

Mean (SD)	n	PRE	n	POST	Mean difference
UC	44	141.8 (17.6)	45	136.0 (17.8)	5.8
e-L	46	143.3 (19.0)	45	133.6 (13.2)	10.3
e-L + W	32	141.5 (17.9)	31	133.6 (16.5)	7.9

b. Mean Diastolic blood pressure, mmHg (n enrolled=133)

Mean (SD)	n	PRE	n	POST	Mean difference
UC	43	83.4 (10.5)	45	81.7 (10.9)	1.7
e-L	46	83.6 (10.0)	43	81.7 (10.2)	2.1
e-L+ W	32	81.0 (13.8)	31	78.6 (10.9)	2.5

c. Mean Glycated Haemoglobin % (n enrolled =86)

Mean (SD)	n	PRE	n	POST	Mean difference
UC	25	8.0 (2.07)	19	7.87 (1.62)	0.13
e-L	21	8.1 (1.66)	16	7.4 (1.31)	0.69
e-L + W	20	7.7 (1.35)	14	7.35 (1.18)	0.35

d. Mean LDL mmol/L (n enrolled =88)

Mean (SD)	n	PRE	n	POST	Mean difference
UC	24	2.9(0.93)	19	2.35(0.97)	0.55
e-L	29	2.86(1.04)	19	2.77(2.24)	0.098
e-L + W	15	2.62(0.86)	11	1.65(0.53)	0.96

e. Mean TC/HDL mmol/L (n enrolled=88)

Mean (SD)	n	PRE	n	POST	Mean difference
UC	24	4.13(0.87)	19	3.63(1.09)	0.49
e-L	29	4.12(1.34)	17	3.50(0.88)	0.62
e-L + W	15	4.52(1.37)	12	3.77(1.34)	0.75

3.4. Discussion & Conclusion

3.4.1 Discussion

This randomized controlled trial showed that a web-based communication intervention positively impacts reaching treatment targets for primary care patients. We focused on a patient population not often included in communication studies. Specifically our intervention was aimed at "non at target" chronic disease patients with hypertension, type II diabetes and/or dyslipidemia.

Patients who received the web intervention were more likely to be within guidelines as compared to patients who received usual care. This effect remained statistically significant in our liberal sensitivity analysis, and showed a trend towards significance in our conservative sensitivity analysis (worst-case scenario). Considering Internet use is rapidly increasing in age groups of 55-64 years old, where more than 90% of users accessed the Internet in 2016 (The Canadian Internet, 2015), the use of web technology is an applicable and feasible way to change communication even in long-standing relationships (Lussier et al., 2016), and can be integrated as a useful tool in the PC toolbox.

Communication interventions have rarely shown an impact on health outcomes (Clayman et al., 2016). This is particularly true of cardiovascular risk factors (Schoenthaler et al., 2014) as assessed in our study. Some exceptions are of note (Greenfield et al., 1988; Weitzman et al., 2009; Willard et al., 2015). The first with positive outcome results, Greenfield et al. (Greenfield et al., 1988), is not comparable to our study, because this study's sample was not typical of PC populations. Our study had a patient population with a mean 7.9% pre-intervention HbA1c (vs 10% in Greenfield et al.'s study). Furthermore, other studies that used combined on-target scores show results comparable to those in our study (Weitzman et al., 2009; Willard et al., 2015). However, these interventions, like most communication interventions, are delivered immediately before the consultation in the waiting room. In our study, patients accessed the website and/or workshop a couple of weeks before their visit. This likely diminished the salience of our intervention, and it is thus impressive that our results compare to the literature.

The combined e-L+W group suffered from high attrition and low adherence and did not demonstrate improved control compared to usual care. In a clinical context where it is already difficult for patients to attend follow up appointments (Kheirkhah, Feng, Travis, Tavakoli-Tabasi, & Sharafkhaneh, 2015; Suzanne, Judith, & Celeste, 2004), attending a workshop, despite financial compensation and multiple reminders, was not successful. The high cost and low attendance of workshops render them an unattractive tool for patient communication skills interventions in this setting. Websites may be a preferred alternative, however increasing their uptake is a noted challenge in the literature (Barello et al., 2016; Gee et al., 2015; Krist et al., 2011, 2014).

The use of a heterogeneous multi-morbid chronic disease patient sample in long-term relationships with their physicians was a strength of this study. Multi-morbid patients have more difficulty engaging with their physicians and understanding health information (Friis, Lasgaard, Osborne, & Maindal, 2016). Our sample is more typical of the primary care patient population, compared to most studies, which only focus on single diseases, such as diabetes (Fortin et al., 2005). Perhaps less generalizable to this population is the criterion of computer literacy, which was responsible for declines in participation. We recognize that this tool may not be valid for all PC patients, and may be most effective in patients who are already somewhat engaged in their care.

The focus on patients suffering from at least one of three common chronic diseases in primary care posed a challenge for sub-group analyses, which lacked statistical power to show group differences. However, descriptively, mean changes from baseline to post-intervention for the e-L group as compared to usual care were in the same range as differences reported in meta-analyses of self-management studies (Bolen et al., 2014; Coulter et al., 2015; Pal, 2013; Zhai et al., 2014). These studies are generally more intensive than communication interventions. In our study, HbA1c dropped for all groups. Mean changes for the e-L and the e-L+W groups surpassed changes in usual care (0.69% vs 0.35% vs 0.13%, respectively). These differences are clinically relevant. A 1% change in HbA1c is related to a 20% reduction in mortality. A decrease in 0.7% of HbA1c is comparable to decreases seen in standard medication regimens (Riddle, Ambrosius, Brillon, Buse, & Robert, 2010).

Street et al.'s model posits that improved communication and clarity of explanations increases medication adherence. In this trial, physicians reported seldom changing prescriptions, implying that improved outcomes were the result of improved adherence. Greenfield et al. (Greenfield et al., 1988) similarly reported no significant changes in drug regimens, yet an improvement in patients' information seeking behaviour. The PACE training did change communication about medications: patients in intervention groups had more initiative and spoke more frequently about the "observed effects" and their "attitudes" toward their medications (Lussier et al., 2016). This replicates findings that patients who actively participate in their encounters elicit more information from their providers (Cegala & Post, 2009; Cegala et al., 2007). It is likely that this richer information exchange led to better medication adherence, thus leading to improved hypertension, diabetes and dyslipidemic control. This causal hypothesis however could not be tested because of a difficulty in collecting pharmacy adherence data. Provider attitudes have also been recognized to shape patient participation and activation (Alvarez, Greene, Hibbard, & Overton, 2016; Barello et al., 2017; Greene, Sacks, Hibbard, & Overton, 2016). Randomization of patients in this study ensures that provider attitudes would be equally distributed across groups. Furthermore there were no differences between study groups in physicians' evaluation of patients' skills facilitating productive interactions, as reported in Lussier et al. (Lussier et al., 2016).

This study has several limitations. The attrition rate was significant. A third of the sample did not return for their follow up appointment. The delay between study randomization and assessment at follow-up could have been shorter. Unfortunately, it is not atypical of primary care practices to witness a high degree of no-shows (Kheirkhah et al., 2015; Suzanne et al., 2004). Completer analysis is common in communication studies, and many do not report how they treat missing data (Schoenthaler et al., 2014). Although loss to follow up is a concern for internal validity, sensitivity analyses were performed in order to mitigate this bias. The assumption that patients who do not return for follow up are not meeting their treatment targets is supported by the fact that patients who do not return are often poorly controlled (Paterson, Charlton, & Richard, 2010). The use of an inactive control is another limitation of this study. It is thus difficult to assess which component of the intervention impacted health outcomes. Future studies would benefit from choosing active control groups that access

information online, for example. Another limitation of this study, often seen in the literature (Griffin et al., 2004; Schoenthaler et al., 2014), is that it only offers a snapshot of continuous care. Looking at website use and health outcomes over time would provide us with stronger evidence to infer causation. Finally, data was collected from 2009-2010, however we do not believe this to be a major limitation, since our findings compare to the recent literature. Internet access has changed from 2010 compared to now. In 2010, 79% of Canadians had access to Internet compared to 87% in 2013 (The Canadian Internet, 2015). Furthermore, over 60% of Canadians have the computer literacy skills necessary to navigate a website like THT. This percentage increases annually (*Perspectives de l" OCDE sur les compétences 2013: Premiers résultats de l"évaluation des compétences des adultes*, 2013). Increases in Internet access and use suggest that this intervention would be even more acceptable if performed today.

3.4.2 Conclusion

Training patients in communication skills using a website has positive effects on reaching treatment goals for hypertensive, diabetic and dyslipidemic patients. However, the combination of web and workshop did not yield statistically different results compared to usual care. Results must be interpreted with caution due to the potential for bias. Despite these shortcomings, this type of web intervention is easy to use and applicable and has practice implications for patients, physicians and policymakers.

3.4.3 Practice Implications

This type of website can be integrated into primary care practices. It offers the possibility of optimizing doctor patient communication, engaging uncontrolled chronic disease patients in their care and impacting health outcomes. Eventually, these changes have the potential to reduce chronic disease related morbidity. Future communication studies should use rigorous approaches, complete intention to treat analyses and measure health outcomes in validated, continuous ways linking these assessments to objective and validated communication measures. Although the website evaluated in this trial no longer exists, we are currently working on, and studying the implementation of a website inspired from this

intervention. *Discutonssante.ca* is a free and available website in French, with an English translation soon to be available.

Chapter 4: Communication and Patient Participation Influencing Patient Recall of Treatment Discussions

This article, study B, was about a planned secondary outcome of the *Talking Health Together* THT trial. This work has been peer reviewed and published in the open access journal *Health expectations* in November 2016, reprinted here with permission: Richard, C., Glaser, E., & Lussier, M. T. (2016). Communication and patient participation influencing patient recall of treatment discussions. *Health Expectations*. (Richard, Glaser, & Lussier, 2016).

The THT trial was conceived of and designed by my two co-authors, MT Lussier and Claude Richard. They developed the protocol, the study interventions and worked to carry out the study.

I inherited a compiled database. For this particular study, I updated the literature review. I cleaned and organized the database. I actively participated in the discussions of the final recall measure and developed the necessary SPSS scripts by merging two existing variables, one from a questionnaire developed by Drs. Richard and Lussier, and the other variable from MEDICODE. I performed statistical analyses and worked closely with statisticians. I spearheaded discussions about methodological choices and how to present results. Dr. Richard, Dr. Lussier and I worked together closely on many of these aspects, and about the discussion of the data. I wrote up the basic draft of the article. All of us contributed to editing the article. I took the initiative to submit the article to journals and presented our findings at multiple conferences (E. Glaser, Richard, & Lussier, 2015, 2016b, 2016c). Although I contributed significantly to this article, it was Dr. Claude Richard who conceptualized the original post visit patient recall questionnaire and tailored it to the MEDICODE coding system to allow calculation of treatment information recall. Dr Richard also conceptualized the final recall measure used in the study. This is why I am second author for this study.

4.1 Introduction

Chronic diseases (CDs) are increasingly prevalent and contribute significantly to the financial burden of health care (Centers for Disease Control and Prevention, 2014). Patient recall and understanding of pharmacological and lifestyle treatment information received during encounters are key intermediate variables towards better adherence, CD management and improved health outcomes (Bartlett et al., 1984; Jerant, DiMatteo, Arnsten, Moore-Hill, & Franks, 2008; Kessels, 2003; Ley, 1982; Linn, van Dijk, et al., 2013; Pickney & Arnason, 2005; Schillinger et al., 2003; Street, 2013; Street et al., 2009).

Unfortunately, recall is often faulty. Patients remember as little as a fifth of information discussed and immediately forget 40-80% of the content of their medical encounters (Kessels, 2003; Ley, 1979; Sherlock & Brownie, 2014). Factors influencing recall cited in the literature can be classified into three categories: 1) patient, 2) information, and 3) communication. Patient characteristics include age (Jansen, Butow, et al., 2008; Kessels, 2003; Sherlock & Brownie, 2014), education, health literacy (Kessels, 2003; Mccarthy et al., 2013; Ngoh, 2015; Selic et al., 2011; Sherlock & Brownie, 2014) and anxiety (Kessels, 2003; Portnoy, 2010; Sep et al., 2014). Information characteristics include modality (written vs aural) (Glicksman et al., 2014; Kessels, 2003; Meulen et al., 2008; Nicolson et al., 2011) structure (Isaacman, Purvis, Gyuro, Anderson, & Smith, 1992; Langewitz et al., 2015; Ley, 1979; McGuire, Morian, Codding, & Smyer, 2000; Werner et al., 2013), number of instructions given (Bravo et al., 2010; Hall et al., 1988; Selic et al., 2011) and encounter length (Jansen, Butow, et al., 2008). Physicians' communication skills are also related to recall (Bartlett et al., 1984; Kessels, 2003; Morrow et al., 2005; O'Keefe, Sawyer, & Roberton, 2001). Few studies have examined the effect of patients' communication skills on their recall of information.

Authors stress the importance of activating patients (Arnold, Coran, & Hagen, 2012; Cegala, Marinelli, et al., 2000; Dulmen et al., 2008; Greene & Hibbard, 2011; Ricciardi, Mostashari, Murphy, Daniel, & Siminerio, 2013), especially those suffering from chronic diseases (Bodenheimer, Wagner, & Grumbach, 2002; Lussier & Richard, 2008). A few studies aiming to increase patient participation have shown benefits in terms of recall (Dillon, 2012;

Harrington et al., 2004; Post et al., 2002; Sansoni et al., 2015; van Weert et al., 2011). However, the definition of patient participation is unclear. Many studies equate patient participation with patient question asking (Post et al., 2002; Street, 2013). The effect of question asking on recall of information remains equivocal; some studies show no effects (Hall et al., 1988; Jansen, Butow, et al., 2008; Sansoni et al., 2015; van Weert et al., 2011), others show positive effects (Dillon, 2012) or even negative effects (Hall et al., 1988; Jansen, Butow, et al., 2008; Roter et al., 1987).

The main objectives of this study were to describe recall of lifestyle and medication treatment information and to assess what aspects of physician-patient communication and patient participation predict patient recall of medication information, in off target chronic disease primary care (PC) patients. This study is an observational study within a randomized controlled trial. Results from the randomized controlled trial concerning communication have been reported elsewhere (Lussier et al., 2016)

4.2 Methods

4.2.1 Study Design

This study is an observational study within a randomized trial. The clinical trial, NCT00879736, was registered with ClinicalTrials.gov and the protocol received ethics approval from the Institutional Review Board Services (IRB). Informed consent was obtained from physicians and patients. All participants were informed about the confidentiality of their data. There were no transcriptions of audio-recordings. All direct identifying information was numerically coded. The clinical trial was a three arm parallel design that randomized patients into receiving one of the two communication interventions or usual care. Interventions were delivered either through the web only or combined with a workshop. The main objective was to assess the impact of the educational interventions compared to usual care (no additional material) on physician-patient communication. Analyzing group effects for medication information recall was not possible because of the quantity of missing data. Thus, this paper disregarded original group assignment, and reports on patients' correct recall of information about their chronic disease treatments.

4.2.2 Setting and Participants

Patients were recruited from nine urban and suburban community-based PC practices in Ontario (Canada) between March and December 2009, by the study coordinator. The last outcome data was retrieved from patient charts in September 2010.

Participating family physicians (FPs) were chosen using a convenience sample and were considered eligible if they had been in practice at least five years, had a practice orientation toward an adult population, including chronic disease patients, agreed to the audio-recording of one visit per participating patient. Once physicians consented, patients were approached by the study coordinator and enrolled if they consented and met the following criteria: 1) forty years or more of age, 2) ability to speak English, 3) comfortable using a computer for routine activities such as regular access to the web and e-mail, 4) have a routine follow-up visit scheduled within three to four months of study enrollment, 5) allow access to their medical records, and 6) have at least one of the following three CD, hypertension, type II diabetes, and/or dyslipidemia. These CD were diagnosed by their physicians as not meeting treatment targets set by relevant Canadian guidelines (Canadian Diabetes Association Clinical Practice Guidelines Expert Committee, 2003; Khan et al., 2009; McPherson et al., 2006). Pregnant patients or those actively treated for cancer were excluded.

4.2.3 Procedures

Patients were recruited and enrolled at an initial visit. Participating FP completed a basic socio-demographic and practice profile questionnaire at study enrollment. Patients meeting inclusion criteria completed a baseline questionnaire including socio-demographic and clinical data such as length of FP-patient relationship (Safran et al., 1998). Three to four months later, they returned for their follow-up visit with their FP following normal scheduling. This visit was audio-recorded. Immediately following this visit, patients completed a questionnaire that assessed their recall of treatment information they had just discussed with their FP.

4.2.4 Variables & Measures

Predictor and outcome variables that were used in analyses and their sources are described in Table VIII.

Table VIII. Predictor, outcome variables and their source

Variables	Source (Instrument)
Predictor variables	
Patient variables	
Age	Baseline questionnaire
Education	Baseline questionnaire
Number of chronic diseases for which patients were enrolled	Physician questionnaire
Information variables	
Length of encounter	Audio-recording (RIAS)
Medication status	Audio-recording (MEDICODE)
Medication class	Audio-recording (MEDICODE)
Communication variables	
Socio-emotional utterances	Audio-recording (RIAS)
Physician dominance	Audio-recording (RIAS)
Communication control	Audio-recording (RIAS)
PACE composite score	Audio-recording (RIAS)
Dialogue score	Audio-recording (MEDICODE)

Initiative score	Audio-recording (MEDICODE)
Average number of themes discussed per medication	Audio-recording (MEDICODE)
Dependent variable	
Recall of treatment information	Post-visit questionnaire & Audio-recording (MEDICODE)

Audio-recorded encounters were coded with the Roter Interaction Analysis System (RIAS) (Roter & Larson, 2002) and MEDICODE (Richard & Lussier, 2007, 2006a). These two validated coding systems and the following measures are described in detail in Lussier et al. (Lussier et al., 2016). RIAS ascribes an interaction code to all utterances spoken by the physician and the patient during an entire encounter. Codes fall under two large categories: socio-emotional and instrumental utterances. Socio-emotional utterances are types of talk where the participant shows agreement, understanding, empathy, expresses concern, disapproval, or reassurance, for example. Instrumental utterances are types of talk where the participant gives information or counsels on medical conditions, lifestyle issues or treatments. RIAS allowed us to estimate encounter length, measure physician dominance and patient communication control scores, the proportion of utterances that were socio-emotional, and a PACE composite score assessing "ask", "check", "express" utterances. MEDICODE is a content analysis system that codes communication about medications and medical conditions. MEDICODE codes the presence of discussions related to hypertension, diabetes and dyslipidemia. Furthermore, discussions of lifestyle treatment, such as diet, exercise, stress management, tobacco and alcohol were also coded. For medication discussions, six of the ten possible thematic meta categories were judged the most relevant for chronic disease patients to understand and properly adhere to their medications: medication name, instructions (how to take medication), medication main effect (how it works), adverse effects, adherence and concerns. Themes such as "warnings" and "indications to re-consult" were deemed less pertinent in the context of follow up care for long-term patients, where few prescriptions were

new prescriptions. The average number of themes discussed per medication was calculated, giving an indication of the extent of the medication discussion.

Medication status was coded in MEDICODE as: 1) active discussed: medications that patients are taking without need for a new script, 2) renewed prescription: renewing a prescription for an active medication, 3) new prescription and 4) other: medications which are discussed but are not currently being taken (Richard & Lussier, 2006b). For each theme discussed, MEDICODE also codes for interactions, such as who initiates medication discussions and whether there is a dialogue or a monologue. A dialogue score was calculated using the average level of dialogue on medication themes per medication discussed [0=monologue, 1=dialogue]. An initiative score was calculated in the same way [-1=patient initiative, 0=shared initiative, 1=physician initiative].

Three coders, who were blind to group allocation, received an intensive one-month training in both methods and were supervised on a continuous basis during the coding by one of the authors (CR). Inter-rater reliability was calculated on 10% of encounters. Any discrepancies were resolved through group discussion. Average percent agreement for RIAS categories was 90%. Mean Kappa value for MEDICODE was of 0.83, showing good agreement between coders.

4.2.5 Recall of treatment information

Immediately following the encounter, patients completed the post-visit questionnaire. They were asked if they had discussed hypertension, diabetes or dyslipidemia, and if so to elicit the name of all the medications they remembered discussing for each CD. Patients were also asked whether they had discussed the five other medication themes described above (yes/no) in relation to the named medication. Patients were asked whether they had discussed changing their diet, doing more exercise, reducing their stress, cutting down or quitting smoking and drinking less alcohol (yes/no). Patients' answers on the post-visit questionnaire were matched against the MEDICODE coding of the audio-recording. A recall score was created for medication information, with one point awarded for each correctly recalled medication theme. Patients who did not recall the medication name automatically received a score of zero because the questionnaire was only interpretable if it was clear which medication

the patient was referring to. Unintelligible medication names, coded by MEDICODE, were excluded from analysis.

4.2.6 Statistical Analyses

Baseline characteristics and descriptive statistics were analyzed using Chi square tests and ANOVAs. A linear mixed model was performed in order to see what variables predicted recall of medication information. Medication was the unit of analysis clustered within patients. The dependent variable was the combined score of recall of medication information. Variables theoretically related to recall in Table VIII were tested in univariate analyses. Variables significantly related to recall in univariate regressions ($p<0.15$) were inserted into the final multivariate regression as fixed effects. All tests used an alpha level of significance of 0.05.

The sample size used here was based on participants from a randomized controlled trial (n=221) (Lussier et al., 2016). Analyses concerning medication information are based on a subset of the sample that had complete medication recall data (n=159). Statistical analyses were performed with SPSS® version 20.0.

4.3 Results

4.3.1 Socio-demographic and clinical characteristics

A description of the randomization process for the original sample is reported in the primary paper (Lussier et al., 2016). Figure 7 describes the consort flow of patients. This study included 221 patients for lifestyle and medical condition descriptions, analyzed and described in the original paper, and 159 patients for medication discussions. The 62 excluded patients (47 did not discuss CD medications and 15 were unintelligible and thus uncodable) did not differ compared to the original 221 on relevant socio-demographic and clinical characteristics such as education, gender, ethnicity, income, length of relationship with FP, number of visits within the past year, and chronic disease profile. However, excluded participants were significantly older than those included here $F(1, 219)=4.49$, $p=.035$, 60.3(9.1) years vs 57.3(9.3).

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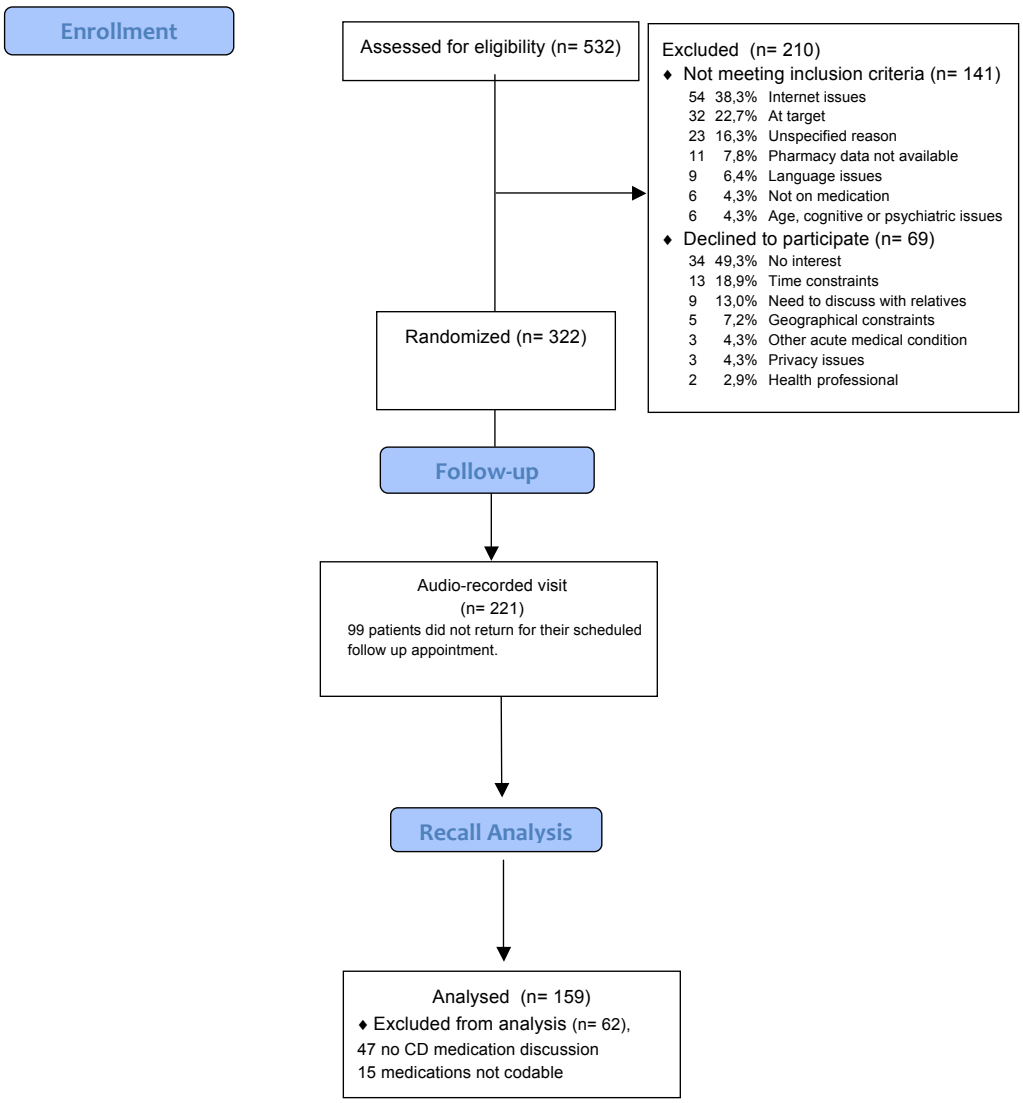

Figure 7. CONSORT Patient flow diagram

The 18 participating family physicians were 51.2 (6.9) years old, predominantly male (14/18) and in practice for a mean of 25.2 (7.0) years. A majority of these physicians worked in group practices (11/18) and saw a mean of 4.5 (1.3) patients per hour (min-max: 2.5–8.0). Table IX shows socio-demographic and clinical characteristics of patients. Patients were in their late 50s, generally high school educated and white. Most participants knew their physicians for longer than five years and had more than four medical visits per year. A third of the sample had more than one active CD. Encounters lasted 10 minutes on average, were physician dominated and had a lower proportion of socio-emotional utterances than information utterances. A small proportion of patients' utterances were question asking, checking or expressing emotions.

Table IX. Socio-demographic, clinical and encounter characteristics at baseline included in the medication recall analyses (n=159)

	n=159 patients
Age mean (SD)	57.3 (9.3)
Gender no. (%) male	90(57)
High school completed no. (%)	116 (73)
Relationship with FP	
Length of relationship with FP no. (%)≧ 5 years	118 (74)
Number of visits in past year no. (%) ≧ 4 visits	105 (66)
Ethnicity no. (%)	
White	118 (75)
Black	9 (6)
Asian	21 (13)
Other	10 (6)
Income $ (CAD) no. (%)	
<20 000	19 (13)
20 000- 39 000	30 (21)
40 000 – 59 999	20 (14)
60 000 – 79 999	27 (19)
> 80 000	46 (32)
Chronic Disease*	
Hypertension no. (%)	95 (61)
Type II Diabetes no. (%)	62(40)
Dyslipidemia no. (%)	64 (41)
1 CD diagnosis no. (%)	109 (69)
2 CD diagnoses no. (%)	32 (20)
3 CD diagnoses no. (%)	16 (10)
Encounter Characteristics, mean (SD)	
Length, minutes	10.2 (4.8)
Proportion of socio-emotional uterrances[a]	33.5 (8.7)
Physician dominance score[b]	1.26 (0.44)
Communication control score[c]	0.97 (0.64)
Proportion PACE like utterances[d]	11.0 (5.5)

Note FP= Family physician. CD=Chronic disease

*Some patients were enrolled for more than one diagnosis, so percentages do not equal 100%.

[a] Percentage out of total physician-patient utterances.

[b]Physician dominance score is a ratio of total physician utterances over total patient utterances. Scores > 1 indicates physician dominance.

[c] Communication control score is a ratio of patient control over physician control. Scores > 1 indicates patient control.

[d]PACE composite score is a percentage of total patient utterances. It is obtained by summation of patient utterances associated with three communication skills Ask, Check, Express. Further details are given in Lussier et al. (Lussier et al., 2016).

4.3.2 Recall of chronic medical conditions and lifestyle treatment discussions

Recall of whether participants discussed hypertension, diabetes and cholesterol is shown in Table X. Hypertension, diabetes and cholesterol were discussed in 83.0% (n=183), 60.1% (n=133), 50.2% (n=111) of the 221 interviews, respectively. Patients recalled approximately 88% of these discussions. Recall of lifestyle treatment is also shown in Table X. Discussions of stress management, tobacco and alcohol reduction were rare, however we do not have information allowing us to evaluate the relevance of these discussions (ie known smoking status). Diet and exercise were discussed in about half of the encounters. Recall of these discussions ranged from 42.8% (alcohol) to 70.0% (exercise).

Table X. Recall of chronic disease problems and lifestyle issues discussed, no. (%) (n=221 patients)

Recall of problem discussed	
Hypertension	160/183 (87.4)
Diabetes	118/133 (88.7)
Cholesterol	98/111 (88.3)
Recall of Lifestyle discussions	
Diet	64/123 (52.0)
Exercise	70/100 (70.0)
Stress	14/24 (58.3)
Tobacco	8/13 (61.5)
Alcohol	3/7 (42.8)

**Note.* The denominator indicates the presence of this topic in the interview as coded by MEDICODE. The numerator indicates the patient's response to a yes-no question of whether they discussed this topic.

4.3.3 Recall of chronic disease medication (CDM) information

The 159 participants analyzed for medication discussions, discussed a total of 401 chronic disease medications (CDMs). Descriptive statistics regarding medication discussions are shown in Table XI. The majority of medications discussed during the encounter were of two main statuses, either actively being taken or re-prescribed, consistent with a CD population. Discussions were mostly initiated by physicians and had a low dialogue score. Medication discussions were not extensive in terms of the number of themes discussed. The most often discussed theme besides the name was instructions, mentioned in less than half of the medication discussions.

Table XI. Characteristics of medication discussions (n=159 patients)

	N=401 medication discussions
Medication class no. (%)	
Hypertension	175 (43.6)
Diabetes	122 (30.4)
Cholesterol	104 (25.9)
Medication Status no. (%)	
Newly prescribed	17(4.2)
Active discussed	247 (61.6)
Renewed prescription	65 (16.2)
Other	72 (18.0)
Frequency of Theme no. (%)	
Instructions	193 (48.1)
Adverse effects	121 (30.1)
Main effects	139 (34.7)
Adherence	90 (22.4)
Attitudes and emotions toward medications	46 (13.9)
Number of Themes discussed, mean (SD)	2.5 (1.2)
Dialogue[a] mean (SD)	0.28 (0.23)
Initiative[b] mean (SD)	0.47 (0.63)

Note: *445 chronic disease medications were discussed. In 15 encounters 44 of these medications were not identifiable and were excluded from analyses.

[a]Dialogue score ranges from 0-1, where 0 is a monologue and 1 is dialogue

[b]Initiative score ranges from -1 to 1, where -1 is patient initiative and 1 is physician initiative.

Figure 8 shows recall of medication themes. Patients were able to correctly elicit the name of the medication for less than half of the 401 medications just discussed. When patients did not correctly identify the medication name, they were coded as incorrectly recalling the five other medication themes (in patterned red). Patients that did not remember discussing a specific medication theme, despite recalling the medication name are also shown (block red). In green is correct recall. Each theme was approximately correctly recalled a third of the time (eg. 65/193 for instructions). Figure 9 shows the distribution of the number of themes correctly recalled. Patients recalled less than one theme on average.

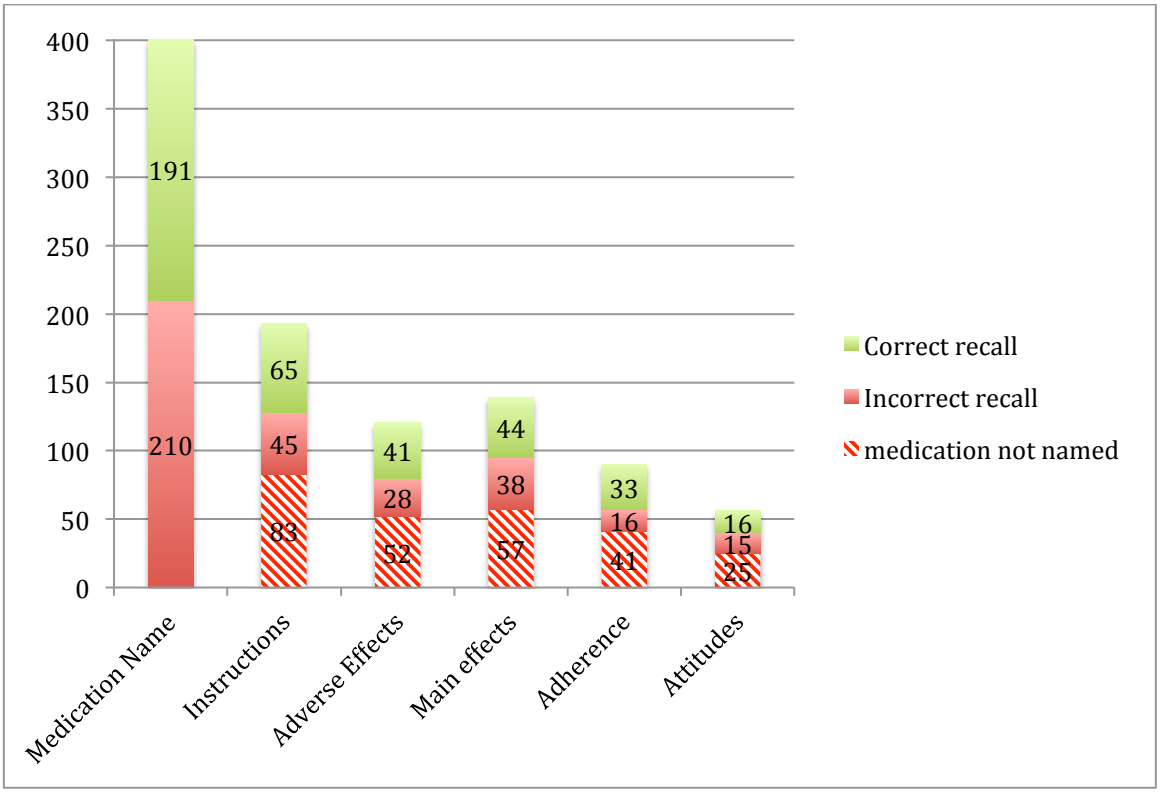

Figure 8. Recall of medication information, no. (%) (n=401 medication discussions, from n=159 patients)

**Note.* The Y axis denotes the frequency of discussion out of the 401 medication discussions as coded by MEDICODE, see Table XI. Green is the proportion of patient's correct recall of discussing information. Red is patient's incorrect recall of information when they were able to elicit the medication name. In patterned red is when the theme was objectively discussed, but patients could not name the medication, and is thus considered incorrect recall.

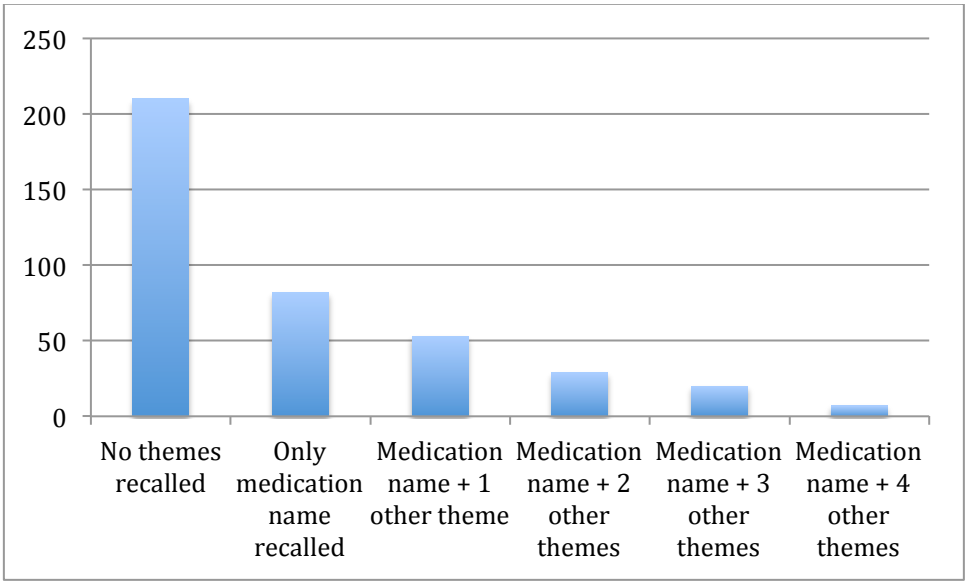

Figure 9. Distribution for the frequencies of medication theme recall (n=401 medication discussions, from n=159 patients)

Table XII shows the results of the linear mixed model. First, we examined the relationship between the three types of variables (patient, information and communication characteristics) and patient recall in univariate regressions. We found no statistically significant relationship between recall and education or number of CD. For information characteristics, the length of encounter and medication class were not related to recall. Communication characteristics of physician dominance and socio-emotional utterances were not related to recall.

The multivariate regression showed that while adjusting for relevant patient and information variables, certain aspects of communication were predictors of recall. The extent of discussions (the average number of themes discussed) as well as increased dialogue and patient initiative were all significant predictors of greater medication information recall. The information variables of medication status showed that new prescriptions were better recalled than active prescriptions.

Table XII. Linear Mixed Models for variables influencing correct medication information recall

Variable	Beta Estimate [95% CI]	P value
Age	-0.014[-0.029, 0.00]	0.057
Medication status discuss/exclude vs active	-0.17 [-0.47,0.12]	0.25
Medication status renew vs active	0.19 [-0.13, 0.51]	0.24
Medication status new prescription vs active	0.88 [0.34, 1.42]	0.002
PACE	0.013 [-0.011,0.038]	0.29
Communication control	0.085 [-0.12, 0.29]	0.41
Presence of Dialogue	0.59 [0.088, 1.08]	0.021
Patient Initiative[b]	-0.22[-0.39, -0.04]	0.015
Average number of medication themes	0.48 [0.39, 0.58]	P<0.001

[b] Initiative scores go from -1 [patient initiative] to 1[physician initiated].

4.4 Discussion

Recall is an important mediating variable for improved treatment adherence and health outcomes (Kessels, 2003; Ley, 1979; Street et al., 2009). This study focused on recall of both lifestyle and pharmacologic treatment information deemed crucial for the optimal management of CD. One of the strengths of this study is its focus on long standing CD patients followed in PC and not reaching guideline suggested outcomes. Recall was assessed immediately after the medical encounter.

4.4.1 Type of recall measure

The heterogeneity of recall measurements has been recognized and has a major impact on the evaluation of recall (Ley, 1979; Sherlock & Brownie, 2014; Watson & McKinstry, 2009). The results of our study confirm this. Correct recall of treatment information in this sample ranged from less than 34% to 88% depending on what was being recalled and how recall was measured. This range is consistent with the bulk of published research (Dillon, 2012; Kessels, 2003; Ley, 1979; McKinstry et al., 2011; Meulen et al., 2008; Pavlik, Brown, Nash, & Gossey, 2014; Sherlock & Brownie, 2014; Derjung M. Tarn & Flocke, 2011; Watson & McKinstry, 2009). Recall was high for a general question such as remembering discussing hypertension. However, recall of specific discussions, such as exercise and diet in relation to the CD, dropped respectively to 70% and only 50% of patients remembering discussing these issues.

Recall scores are higher for yes-no or multiple choice type questions, than for open ended questions asking patients to elicit information (Jansen, van Weert, et al., 2008). This has been replicated in our study, where eliciting the medication name had lower recall scores than yes-no questions regarding either medication themes or specific lifestyle issues. Considering that yes-no questions are more easily answered than open ended questions, it is of potential concern that only half of patients remember whether or not they discussed diet. This makes one wonder how many would be able to remember specific elements of their diet discussion so important in the management of the three CDs this study focused on.

4.4.2 Recall of medication information

For medication information, the recall score used here was relatively strict, because patients who did not recall medication names were automatically given a score of zero for the other themes. This way of scoring recall may in fact underestimate level of theme medication recall, however questions were still yes-no as described above. Patients correctly remembered discussing one medication theme, when 2.5 themes were discussed on average. Patients were able to elicit less than half of the names of medications that they had just discussed with their providers. Medication names are frequently the best recalled items (Isaacman et al., 1992; Langewitz et al., 2015; Linn, van Weert, Smit, Perry, & van Dijk, 2013; Pavlik et al., 2014). A common concept throughout history and across cultures is the idea that knowing the name of something gives one power over it (Graham, 2011). Naming, thinking and apprehending reality are intimately related (Lau, Lee, & Chiu, 2004). Medication names are an important way to establish shared language between patients and physicians and are instrumental in empowering patients to reflect upon, understand and manage their health (Bajcar, 2006; Stevenson, Cox, Britten, & Dundar, 2004; Tarn, Mattimore, & Wenger, 2007).

Discussions of the six themes deemed most important for a CD patient to properly take and adhere to their medication do not occur frequently. Less than half of medication discussions include instructions about how to take medications, and adherence is mentioned in only about a fifth of discussions. Although it is possible that FPs did not deem necessary to repeat instructions in these actively taken or represcribed medications, this is questionable considering these patients were not at target. Furthermore, patients only remember about a third of these discussions when they actually do take place.

Although concordant with the literature, the low recall scores of medication information is concerning considering the characteristics of our sample. These CD patients were off target and in long-term relationships with their FPs. These are precisely the patients that need to be mobilized to properly manage their own care. Patients were generally discussing medications that they were actively taking. Many patients did not even discuss CD medications (47/221) during the audio-recorded follow-up appointment. These patients were older than the rest of our sample, and it is troubling to see that medication discussions may be eschewed in older patients. Admittedly, one encounter does not capture continuous care. Yet,

considering the low rate of recall, discussing relevant medications at each consultation would seem indicated for off target CD populations.

4.4.3 Patient participation and medication information recall

Beyond describing recall of treatment information, an aim of this study was to assess which communication and patient participation variables predict medication information recall. There is a need in the literature to be clear about how we define patient participation (Pulvirenti, Mcmillan, & Lawn, 2011; Street, 2013). In this study we used two different coding systems with different underlying assumptions about patient participation. RIAS is an interaction based coding system. It codes each physician and patient speech act into two meta-categories: instrumental and socio-emotional. Each speech act is then assigned to a *large* content domain such as medical condition, treatment, lifestyle or psychosocial etc. Participation is classically conceptualized in this system as an aggregate of different types of physician and patient utterances, such as physician dominance and communication control, describing a general pattern unrelated to specific content. Participation can also be defined, as we have done in this study, as PACE-like interactions reflecting specific information seeking and clarification behaviours. MEDICODE, on the other hand, is a content-based coding system. It first codes for specific content such as medication name, instructions, main effects, etc. Each content element identified is then described in terms of interaction: who, of the two interlocutors, initiated the content, and how much dialogue occurred for that specific theme. Thus, measurement of participation in this second coding system is intimately linked to specific content discussions.

RIAS scores of socio-emotional utterances, physician dominance, communication control and the PACE score, measuring "ask", "check", and "express" utterances, were not found to be predictors of patient recall. It is possible that these patient participation measures were not predictors of patient recall because RIAS participation scores reflect a more "global" measure of the *whole* encounter. This does not capture the subtle variations of patient participation in specific discussions of medications (Richard & Lussier, 2007). It is possible to look at RIAS measures in light of Giddens' theory of practical and discursive consciousness. RIAS measures, because they reflect interactional styles and processes, can be seen as

belonging to the order of practical consciousness. Practical consciousness is knowledge that is inherent in everyday actions, often unnoticed. Talking in a socio-emotional way is something that patients and physicians do, without always realizing they are doing it. Discursive consciousness reflects knowledge that is verbalized, and is thus often better remembered. Content that has been coded by MEDICODE, for example, can be associated with discursive consciousness, and may be more easily remembered (Giddens, 1984).

In this study, greater patient initiative and greater dialogue about medications, measured with MEDICODE, were predictors of patient recall. A known cognitive phenomenon, the "generation effect", stipulates that active involvement in producing information improves recall compared to passive reception (Slamecka & Graf, 1978). Authors suggest that this effect may be due to an egocentric bias and a more accurate monitoring of one's contributions to the production of content (Baroni & Nicolini, 1995; D'Urso & Pascotto, 1991; Jarvella & Collas, 1974; Knutsen & Le Bigot, 2015). When there is patient initiative and dialogue, patients produce information and are actively involved in the discussion. This finding lends importance to developing skills in improved information exchange (Richard & Lussier, 2013). A recognized tool for promoting patient recall called "teach-back" is effective in increasing patient recall of information (Bravo et al., 2010). With this technique, physicians ask patients to reformulate recommendations using their own words. This uses the cognitive resources described in the "generation effect". Unfortunately, providers infrequently use recall promoting techniques, such as "teach-back", that aim to involve the patient (McKinstry et al., 2011; Schillinger et al., 2003; van Dijk et al., 2015).

Our sample of CD patients who were familiar with their FPs benefited from greater extent of information, replicating findings from other studies. The more medication themes were discussed, the better patients recalled medication information. Other studies have found information provision to be an important predictor of recall (Hall et al., 1988; Roter et al., 1987). However, too much information can overwhelm patients (Bravo et al., 2010; McGuire et al., 2000; Tarn & Flocke, 2011), an effect that may be mitigated by an established relationship with FPs. Discussing multiple themes surrounding a treatment deepens and adds density to the conversation. This extensive approach to the discussion can enable more conscious involvement.

Of note, new medication prescriptions were better recalled than active prescriptions, which may explain why Tarn et al found recall rates upwards of 80% in their examination of new prescriptions (Tarn & Flocke, 2011). New prescriptions are accompanied with a greater provision of information than active prescriptions (Richard & Lussier, 2006), which may contribute to their better recall. Furthermore, new prescriptions are distinct compared to active prescriptions for this population, and distinct items are often better remembered (the Von Restorff effect) (Hunt, 1995).

Despite the above noted importance of information provision, medication discussions were often not extensive. Themes that help patients understand what their medications are and why they should be taking them (Bajcar, 2006; Richard & Lussier, 2006) are seldom discussed. Shared decision making is hailed as the future of medical consultations. However, there cannot be any shared decision making if there isn't a sufficient information exchange. Street has described three ways of assessing the quality of information exchanges. One is through message properties, such as the content and form of communication. One is through the process of co-construction of messages and the third is through the outcomes of the information exchange (Street, 2016). We have included all three ways of measuring this information exchange, by using RIAS and MEDICODE to assess the content and form, by using dialogue and initiative scores to assess co-construction and by assessing recall as the outcome of the information exchange. This study shows the importance of having an information exchange that covers essential information about medications. Furthermore, information cannot simply be passively transmitted, as a physician initiated monologue, but needs to be co-constructed with the patient.

4.4.4 Generalizability

This study had a heterogeneous multi-morbid CD patient sample in long-term relationships with their FPs. This sample is typical of the adult primary care patient population, compared to most studies, which only focus on single diseases, such as diabetes. We are confident that the observations reported are generalizable to community-based family physicians. Firstly, physicians were given no instructions beyond the fact that they were participating in a communication study. Their interview schedules were not modified for the

study and the average length of encounters was comparable to Ontario average PC visit lengths. Perhaps less generalizable to this population is the criterion of computer literacy. However computer literacy is rapidly increasing in age groups of 55-64, where more than 70% of users access the Internet (Statistics Canada, 2012).

4.4.5 Limitations

This study has several limitations. Firstly, a selection bias cannot be excluded. Participants were chosen according to eligibility criteria for the randomized controlled trial that was being conducted. Furthermore, sixty-two patients from the original sample (n=221) (Lussier et al., 2016) were excluded from analyses because they did not discuss chronic disease medications (n=47) or CDMs were not identifiable (n=15). Despite participant loss, most baseline factors remained equivalent. This study is not exempt from a possible Hawthorne effect because consultations were audio-recorded. However, studies have shown that the Hawthorne effect is negligible in physician-patient communication research (Coleman & Manku-Scott, 1998; Pringle, Robins, & Brown, 1984; Pringle & Stewart-Evans, 1990; Redman, Dickinson, Cockburn, Hennrikus, & Sanson-Fisher, 1989). In addition, it is possible that this study suffers from misclassification bias. The score used to assess recall was strict, and was dependent on a questionnaire that was specifically developed for this study. Questionnaires used to assess recall are often not validated, and further research would benefit from the validation of a measure designed to assess treatment information recall.

A further limitation of this project is that data was collected in 2009-2010. However, we esteem that there has not been significant changes in the practice of medical interviewing, nor in the practice of website use by patient populations similar to the ones recruited in our sample. Web interfaces similar to what was developed in our project *Talking Health Together* (THT) do exist. In fact, some of these interfaces are more interactive than what was developed in our project. This suggests that the impact seen in the THT study underestimates the potential impact of similar web tools. We have little reason to believe that the behaviour of patients and physicians currently differs from what was observed during our project. Recent projects using MEDICODE show that physician-patient communication is similar to what was

described in the original MEDICODE studies and in the THT study (Johnson Girard & Lussier, 2016; Lussier et al., 2016; Richard & Lussier, 2006; Sibley et al., 2011).

Patient involvement and engagement in the development of the THT website was indirect. A committee of experts, including clinicians and physician-patient communication researchers, was consulted for the development of the intervention content and the trial format. The website interface was iteratively tested with laypersons in order to adjust the format (font, navigation, etc.) and content of the site. The value of the approach used in THT has been confirmed by results of a validation study of a francophone website « *Discutons Santé* » ("Lets Discuss Health"). This website was based on THT. Patients were consulted throughout the development of this website, including a pilot test of the penultimate version. The implementation of this website into routine clinical use in primary care is currently taking place, a major practice implication of the THT study. Preliminary results from focus groups show that the website is greatly appreciated by patients (Lussier, Richard, Boivin, Boustani, Hudon, Levert, Thoer, Jbilou, & Diallo, 2015; Lussier, Richard, Boivin, Boustani, Hudon, Levert, Thoer, Jbilou, Diallo, et al., 2015).

4.5 Conclusion & Practice Implications

The aims of this study were to describe treatment information recall and to assess which communication and patient participation variables are related to medication information recall for off target CD patients. Providers cannot take for granted that long term off target CD patients know and remember treatment information. This is particularly relevant considering the aging demographics of PC populations. Elderly patients were less likely to discuss their CD medications and had poorer recall when they did. Further research is needed to understand the dynamics between aging patients, medication discussions and recall. There is a lack of shared language and empowerment in managing one's disease. Encounters with CD patients need to engage in an explicit conversation about relevant lifestyle modifications and medications (Richard & Lussier, 2013). This conversation should ideally be thorough and engage patients in a true dialogue. Providers and patients need to engage more frequently about treatment information in ways that encourage patients to be active participants in the discussion. Improved discussions may impact treatment information recall. This is an

important step towards improved self-management, adherence and eventually better health outcomes.

Chapter 5: Discussion

5.1 How communication heals: a pathway toward improved control of chronic diseases

This dissertation reported on secondary outcomes of a randomized controlled trial designed to assess an intervention to improve patient communication skills. In the original clinical trial, patients were randomized to either access a communication skills module on the web, or to receive the web intervention as well as a coaching session or received care as usual. The impact of these interventions on physician-patient communication, the main outcome of the trial, has been reported elsewhere (Lussier at al, 2016). In this dissertation, study A reports on the impact of the interventions on reaching treatment targets for hypertension, diabetes and dyslipidemia. Study B reports on patient recall of treatment information. Study B is an observational study within the original trial, and examines which communication variables predict patient recall of information.

These three studies together examine aspects of the model "how communication heals". We have used this broad model to describe a specific pathway toward improved control of chronic diseases. The PACE training offered by THT aims to improve physician-patient communication processes through increased patient participation. Theoretically, improved communication leads to a virtuous cycle improving the proximal outcome of patient recall of treatment information, which leads to better medication adherence, which in turn leads to improved health outcomes such as hypertension, diabetes and lipid control (see Figure 2). This model is used as an in-depth examination of how an effective information exchange between clinicians and patients can lead to better health outcomes. We discuss this model in relation to our findings below.

5.1.1 Does the PACE intervention lead to an effective information exchange?

To answer this first question we need to take a step back and to rapidly review the results related to the primary outcome of this RCT, which was observed communication and

patient participation. In a previously published article (Lussier et al., 2016), we showed that patients completing the PACE training had more effective information exchanges with their clinicians.

Street has proposed that an effective information exchange can be measured in three different ways (Street, 2016). One is through message properties, such as the form and content of what has been communicated. Second, is through the process of co-construction, where patients and providers communicate together to achieve mutual understanding. Finally, effective information exchanges can be measured through an outcomes approach, such as assessing recall, understanding and/or reaching treatment goals. In this trial, we measured information exchanges in these three different ways.

Using the Roter Interaction Analysis System, we evaluated information exchanges through the "form" of communication. Patients who received the combined workshop used more PACE like utterances (asking questions, checking information, expressing concerns) and had more socio-emotional type utterances. MEDICODE allowed us to measure information exchanges by the content broached. Patients who received the web and the combined interventions discussed more themes that reflect the patient experience compared to those in the usual care condition. For example, they spoke more frequently about the observed effects of their medications and their attitudes and emotions toward these medications. Finally, we used MEDICODE to measure the extent that conversations were co-constructed. Patients in intervention groups took more initiative when speaking about contra-indications, dosage & instructions and their attitudes and emotions about their medications. They also had more dialogue when speaking about adherence toward their medications. These results show that patients participated more actively in the medical encounter after having completed the PACE training. A simple communication intervention, whether it is delivered through the web or combined with a workshop, is successful at increasing patient participation and changing physician-patient communication processes. These changes can be reflected in the form and content of communication, as well as in favouring co-production of content. The PACE intervention was successful in changing certain conversations that have traditionally and empirically been solely physician monologues: a passive transmission of information (Geist & Dreyer, 1993; Richard & Lussier, 2007).

5.1.2 Effective information exchange and the proximal outcome of recall

Study B, reported in chapter 4 of this dissertation, did not directly assess whether PACE training had an impact on medication recall. Unfortunately, the quantity of missing data made that type of analysis less feasible. However, we did examine whether general communication variables and specific variables enhanced by the PACE training were predictors of better medication information recall.

This study focused on six medication themes deemed important for patients' adherence to treatment: medication name, instructions (how to take medication), medication main effect (how it works), adverse effects, adherence and attitudes/emotions. For each medication discussed, only 2.5 themes were broached. Patients correctly recalled less than one theme. Discussions that were characterized by increased dialogue, greater patient initiative, and a greater number of themes covered, were predictors of better medication information recall. As described above, the PACE training did encourage greater patient initiative and dialogue, and promoted the discussion of more medication themes. Although we did not directly evaluate the effects of PACE on medication information recall it is likely that the communication changed by this intervention could positively affect recall.

Literature surrounding treatment information recall paints a relatively morose picture that is echoed in our results. As mentioned in Chapter 4, most information discussed is quickly forgotten (Kessels, 2003; Ley, 1979; Sherlock & Brownie, 2014). An effective information exchange can partly remedy this situation and certain actions taken by physicians or patients can improve information recall (Bartlett et al., 1984; Kessels, 2003; Morrow et al., 2005; O'Keefe et al., 2001). Physicians using teach-back can encourage patients to reformulate their take home messages (Bravo et al., 2010), thus encouraging the effective cognitive strategy of generating information (Slamecka & Graf, 1978). Similarly, patients can take the initiative to ask questions, repeat information, write down instructions, and check their understanding. These are all skills encouraged by the PACE training, and although few studies examine these skills, evidence tends to fall in their favour and this could potentially improve medication information recall results.

5.1.3 Does improved treatment recall impact adherence?

The link between recall and treatment adherence has largely been argued from a common sense and theoretical perspective (Kessels, 2003; Ley, 1982; Watson & McKinstry, 2009). Kessels describes Ley's theoretical model where understanding predicts recall. Both understanding and recall of information predict adherence (Kessels, 2003). These relationships were not empirically tested in the review by Ley (Ley, 1982).

Some empirical studies do show associations between recall of treatment information and medication adherence (Bartlett et al., 1984; Linn, van Dijk, et al., 2013; Pickney & Arnason, 2005). Bartlett and colleagues found an association between recall of treatment regimen and adherence. Physician provision of information and instructions were also related to recall of medication information (Bartlett et al., 1984). These results are similar to those found in our study described above. Similarly, Schillinger et al., found that assessing recall in patients through the use of "teach-back" was related to better glycemic control (Schillinger et al., 2003).

More research is needed to clearly link information recall to medication adherence. Furthermore, it is important to recognize that remembering what has been discussed is different from understanding what has been discussed and knowing what to do. Medical knowledge has been correlated with information recall (Ley, 1982; Ley, 1979), yet the two are distinct constructs. Do links between information recall and adherence still hold when we examine understanding and knowledge? Further research that empirically investigates links between recall, knowledge and understanding with treatment adherence is an important step in elucidating the mechanisms of how communication heals. Adherence was a planned secondary outcome of our randomized controlled trial. Unfortunately, technical difficulties made it impossible to obtain this data. Thus, we could not empirically test the relationship between recall and adherence.

5.1.4 Effective information exchange and adherence

Patient-centered communication has been related to medication adherence (Zolnieerek & DiMatteo, 2009). As mentioned above, we could not directly test whether the PACE

intervention was related to medication adherence. However, participating physicians indicated few changes to the patients' drug regimens, and no differences between treatment groups for these changes. This implies that improved control was related to improved adherence rather than a change in medication regimen.

The communication changes described above may likely have impacted adherence, and would thus be responsible for improvement on reaching target goals as shown in the study A of this dissertation described in chapter 3. We will interpret these communication changes and their potential impact on medication adherence and achieving target goals using the CIM "Convaincre et éduqer, Implanter, Maintenir" (Richard & Lussier, 2016) model, which builds on the The Health Belief Model (HBM) (Rosenstock, Strecher, & Becker, 1988).

Health Belief Model (HBM) and "Convaincre et éduquer, Implanter Maintenir" (CIM)

The CIM model describes four beliefs or expectations that need to be evaluated in patients who are in the process of health behaviour change. Patients have to be 1) convinced that they have a health problem and educated about it, 2) convinced that the problem is serious, 3) convinced that there is an effective treatment for their health problem and 4) believe that they are capable of implementing the health treatment in their daily lives. These aspects relate to expectancies about environmental cues, outcomes and self efficacy beliefs, which were integrated into the HBM specifically to reflect the reality of chronic diseases (Rosenstock et al., 1988).

The first two aspects described above relate to beliefs about health problems and the last two reflect beliefs about treatment. The two articles of this dissertation are generally concerned with treatment. We have focused on patients who have long-term chronic diseases. The patients in our sample were in relationships with their physicians for more than five years. Thus, it is reasonable to expect that they were aware and convinced of their diagnoses. These patients were chosen because they were off target. There was a problem regarding their treatment. It is possible that some of the patients in our sample were not convinced of the seriousness of their health problem. It is most likely that patient beliefs of whether their treatments were effective and their self-efficacy regarding their treatment taking needed to be revisited.

The last two aspects of the CIM/HBM model can be further developed using Bajcar's grounded theory about patients' medication taking practices (Bajcar, 2006). This theory was developed through research about patients on long-term medications. It describes three inter-related categories: 1) "making sense of medications", 2) "medication-taking acts" and 3) "medication-taking self-assessment". Making sense of medications is a continual process that begins with patients' understanding of their illness, integration of new knowledge into pre-existing conceptions, and then integration of their experiences of taking their medications. The concept of "sense-making" is directly related to the idea of patients' beliefs about the effectiveness of their treatment, described in the CIM model. "Sense-making" was conceptualized as the most important category in Bajcar's model, as it directly influenced "medication-taking acts" and "self-assessment". Patients examined the medication's effectiveness, adverse effects, their illness status, and the outcomes of their self-care. These self-assessments were then incorporated into their "sense-making" of their medications. "Self-assessments" can be seen as a form of evaluating patient's self-efficacy in their medication taking acts, as described in the CIM model. In Bajcar's study, adherence was particularly problematic when there were inconsistencies in patients' medication "sense-making". Participants in these problematic situations sought information, desired more complete discussions with their health care providers, and often experimented with their medications on their own to create a logical understanding of their medications. Bajcar (Bajcar, 2006) suggests that when patients understand their illness and appropriately interpret their experience of being on medications, they are better able to create coherence and engage in satisfactory "medication-taking acts". This grounded theory, close to data, is similar to the health belief and CIM models.

It is possible to situate MEDICODE's content themes within Bajcar's model of medication-taking categories (Lussier et al., 2016; Richard & Lussier, 2007). Patients who underwent the PACE training spoke more frequently of the observed effects and their attitudes/emotions toward their medications. These are aspects of medication self-assessment. Patients also took more initiative and engaged in a greater dialogue surrounding themes related to medication-taking acts, such as dosage/instructions, adherence towards medications and contra-indications. Furthermore, discussing more of these themes contributes to better

recall of treatment information. It is possible that better recall of information is an indicator or a proxy for medication "sense-making". In other words, patients discuss their medications more thoroughly with their physicians are perhaps better equipped to make sense of what their medications are for. This in turn may contribute to a greater ability to remember what treatment information has been discussed, because this information is likely better organized into their existing medication understanding.

We can hypothesize that these changes in communication allowed patients and providers to discuss expectancies related to their treatment that are essential in changing their medication taking practices. Practitioners and patients who engage in a more explicit conversation about treatments can grapple with patients' beliefs and sense-making about their treatments.

Engaging in this explicit conversation is compatible with models that emphasize patient expertise, such as the Montreal Model (Pomey et al., 2015). Patients are best placed to speak about whether they believe a treatment is effective for their health problem and whether they can properly implement such a treatment. Partnering with them in approaching and developing these subjects is primordial. Bajcar's model already puts this spin on the Health Belief model. The PACE trial further shows that articulating the importance of patient expertise and partnering with patients when discussing treatments is an important and necessary step toward better treatment adherence.

5.1.5 Does the PACE training improve health outcomes?

The first study presented here showed that the PACE training, delivered through the web, has a positive impact on reaching treatment goals. The link between communication interventions and improved hypertension, diabetes and dyslipidemia control is not often studied. Few investigations report positive results. Although the findings of this study need to be interpreted with caution because of losses to follow up, the results are encouraging. For patients completing the web intervention, the number needed to treat is 5.36 for the original analysis and 6.8 for the intermediate analysis. Essentially, for every 7 off-target patients who complete the web PACE intervention one patient will achieve hypertension, diabetes and/or dyslipidemic control.

Web and workshop communication interventions

One of the surprising findings of this study was that the group receiving the combined intervention did not perform as well as the web group. This has been discussed in chapter 3. A recent intervention also found a combined coaching and booklet to be ineffective compared to booklet alone for increasing patient participation (Eggly et al., 2016). Similar to our study, they suggested that patients might prefer to work through material on their own rather than with a coach. However, it is important to recognize that the type of coaching offered differs from study to study. Coaching which is inaccessible is likely less ideal compared to coaching better tailored to patients' needs. For example, peer coaching, where patients receive education from other patients with similar diseases, with whom they maintain regular contact at their own discretion, has been shown to be effective, especially with regards to reducing HbA1c (Thom et al., 2013).

Compared to coaching, web interventions offer the increased possibility for autonomy, because patients work through material on their own. As discussed in section 1.3.2 and 1.6.6, the Internet is where patients gain health information. It is already a tool that reduces the asymmetry between patients and physicians. Proponents of self-management have been developing and studying web interventions. Similarly, electronic health records and portals are also being studied as a way to encourage patients to take on a more active role in their health. However, these types of tools have shown hurdles in terms of patient uptake, with some studies showing that only 15% of possible users access their electronic health records (Barello et al., 2016; Gee et al., 2015; Krist et al., 2011, 2014). One way to increase uptake is for tools to be perceived as integrated in the patient's care (Krist et al., 2014). Because of the single blind design of this trial, THT was not physician recommended and integrated into care.

Talking Health Together was unique in that it was a website specifically designed to enhance communication between physicians and patients, rather than other electronic tools which are geared more toward self management and/or disease related education materials. Communication, however, changes over time. This study examined a one time use of the website. It would be interesting to see if patients would continue to use the tool over time, and whether repeated use of the website between visits would have a long-term effect on communication, recall and health outcomes.

It is likely that patients who received the web intervention achieved better control through improved medication adherence as described above. However, these mechanisms were not explicitly tested. Future studies need to examine these mechanisms, yet this is not an easy task. There is a lack of consensus regarding ontological assumptions about communication. Many studies lack clear theoretical guidance, and this significantly impacts measurement.

5.1.6 Difficulties in examining these mechanisms

In this dissertation, effective information exchanges were assessed from a dialogical perspective. Thus, they were considered as exchanges that were co-constructions of interactions. The second study in this dissertation was innovative in that it used two different validated schemes for coding communication. We assessed the quality of information exchange using RIAS and MEDICODE. We described the content and form of communication, as well as co-construction through initiative and dialogue scores. We also assessed communication in an outcome-based way, examining recall and physiological outcomes. For the specific outcome of medication recall, a quality information exchange was one that sufficiently covered content about medications and promoted the co-production of this content. Street & Mazor argue that the communication measures need to be adapted to their specific research questions, since there is not a clear set of dominant measures with strong theoretical underpinnings (Street & Mazor, 2017). The use of different measures and coding schemes, each with clear theoretical roots, and adapted to their specific research questions, was a strength of the studies in this dissertation.

One of the challenges encountered in study A and study B was that the differing approaches of MEDICODE and RIAS lead to differences in measurement. MEDICODE considers that communication is specific to each medication. Variables were coded in relation to medications. RIAS, however, looks at communication in an aggregate view of the whole encounter, and variables were coded per encounter. This was a challenge from an analysis point of view. In order to resolve this analysis issue, we used linear mixed models to cluster medication discussions within encounters. This allowed us to keep the specificity of content discussions coded by MEDICODE, whilst integrating this measure with the encounter based

coding of RIAS. Using two validated coding schemes for communication in a complementary fashion is innovative. We have been explicit about the ontological assumptions of the measures we used, and this allows us to see what measures and which ways of thinking about communication are useful for predicting certain outcomes.

Moreover, the specific outcome of treatment recall is not frequently studied. No valid measure for this construct exists. Recall has been measured in very different ways, and its measurement has a significant impact on the reported rates of recall. In order to move forward in communication studies, we need to agree on valid measures of intermediate outcomes such as recall, understanding and treatment adherence. We need to study these mechanisms using rigorous methodologies. Valid and consistent measures exist for health outcomes and health markers such as glycated haemoglobin and blood pressure. Communication studies need to consistently and rigorously evaluate these outcomes.

5.2 Methodological strengths of the two studies in this dissertation

This randomized controlled trial was designed to address some of the methodological challenges of previous trials. In this study, we clearly reported our randomization process. The definitions of the primary outcome and planned secondary outcomes were clear. Patients could not be blinded to their condition, since the intervention was targeted toward them. However, physicians and outcome assessors were blinded. This included the study personnel who reviewed medical charts and those who coded communication.

Two validated coding schemes for communication were used. The advantages this conferred have been described above. Our intervention and our communication measures were theoretically guided.

Furthermore, this trial used a web intervention, which has significant implications for the future applicability of this kind of intervention. The use of a multi-morbid sample also adds strength to the external validity of this trial.

Randomized controlled trials often fall somewhere on a continuum between highly internally valid lab controlled trials toward more externally valid pragmatic trials (Friedman et al., 2010). This randomized controlled trial exhibited certain strengths of pragmatic trials. The

trial took place in primary care clinics, with multi-morbid chronic disease patients and used an intervention applicable for these settings. Use of patient charts to assess reaching treatment goals is pragmatic, and reflects what physicians use in order to assess whether their patients reach treatment goals.

5.3 Study limitations

Although this trial has many methodological strengths, it was not without limitations. The major limitation of our randomized controlled trial was the significant losses to follow up. As described in the first study of this dissertation, losses to follow up are frequent in primary care trials. However, the moment of randomization in this trial likely contributed to losses to follow up. Randomization occurred early, three to four months before the intervention and before the audio-recorded encounter. Losses to follow up are the major source of bias in randomized controlled trials. This may have contributed to type I error in the first study. However, we did use sensitivity analyses in order to mitigate this bias. The second study describing recall abandoned the randomized controlled trial design because of the quantity of missing data. Losses to follow up influenced the power that we had in order to detect meaningful differences for reaching treatment goals and for assessing recall of medication information. This study already lacked power to assess differences for secondary outcomes. For example, the actual power of our trial to detect the seen differences in medication information recall between groups was 11% (G*Power). In order to detect a difference of 20% in medication information recall, with an alpha=0.5 and a power of 80% we would have needed a total sample size of n=246, which was originally planned for. However, because of losses to follow up, and missing data, only 159 patients had complete medication information recall data.

Furthermore, we were unable to assess all the mechanisms linking communication toward better health outcomes as outlined in the model, because of losses to follow up and the inability to measure adherence.

Finally, this study only offers a snapshot of communication that is taking place within continuous care. Few studies evaluate communication continuously (Griffin et al., 2004; Schoenthaler et al., 2014). Adherence to medications and reaching treatment goals fluctuate

over time, as does communication. Future studies that delve into these changes over time may offer important insight into the relationship between communication and health outcomes.

5.4 Practice Implications

The two studies included in this dissertation have important practice implications.

5.4.1 Norm changing: the physician patient relationship

One of the major barriers to patient participation in medical encounters is related to normative expectations held by patients (Protheroe, Brooks, Chew-Graham, Gardner, & Rogers, 2013). Patients may be reticent to participate in encounters, and view their role as limited (Geist & Dreyer, 1993; Richard & Lussier, 2007). They feel they do not have permission to ask questions (Protheroe et al., 2013). This is especially the case for patients from lower socio-economic groups, and those with low health literacy (Sim, Yuan, & Yun, 2016).

The PACE training offers an opportunity to subtly change norms about physician patient communication and the physician-patient relationship. Without radically changing the structure or the length of medical interviews, the PACE training positively impacts treatment discussions and reaching treatment goals. This intervention legitimizes patients' participation in encounters.

Study B in this dissertation showed that important lifestyle and medication discussions are not frequently taking place. In addition, these discussions are often physician-initiated monologues. Patients may not have developed the expectation to be seen as an expert and partner in their own health care. Asking patients to participate more in the medical encounter may go against certain social expectations. The PACE intervention not only promotes this partnership, but gives patients concrete skills in order to be effective partners, as described in the Montreal Model (Pomey et al., 2015). It trains patients to prepare for their medical interviews, to ask questions, verify their understanding and express their concerns. This subtle change in expectation about a patient's role in their health and in the encounter may help bring about a conversation that addresses patients' beliefs about their treatments and their capability to apply those treatments. When two people in a conversation believe information is

understood, they do not broach those subjects (Grice, 1975). A physician who assumes that his patient is just as convinced about their medications as the physician is, may omit conversations about important medication themes. It is the responsibility of both the patient and the physician to clarify what understanding is shared and where there is no common ground. This is especially important for patients who are not meeting treatment goals. The PACE training conveys this responsibility to patients. This shift in norms fits within the changing physician-patient relationship. There is a greater role for the autonomy of patients and for partnering between patients and physicians.

Patients who had more initiative and greater dialogue with their physicians remembered more medical information. A major practice implication is that physicians need to encourage patients' participation in discussions. It is essential that physicians understand the importance of recognizing patients as experts of living with their diseases and that they respect and actively seek out their patients' knowledge and experiences. Partnering with patients, encouraging their participation and creating an open space where patients feel encouraged to share their experience is an important part of an effective information exchange. Norm changing can encourage patients to be more active partners and can influence physicians to encourage this role. Physicians can use many techniques, such as the use of open questions. Furthermore, they can perform "teach-back". Few physicians use this technique. However, the studies described here, show that these kinds of techniques could have important implications in terms of recall, adherence and health outcomes.

We believe strongly that the results discussed in this dissertation and wider results from the medical communication literature could be more effectively employed in teaching medical students and physicians in continuing education as mentioned in a number of medical communication education papers (Frank, 2005; S. Kurtz, Silverman, & Draper, 2005; Millette, Lussier, & Goudreau, 2004; Neville, 2015; Richard & Lussier, 2016; Silverman et al., 2013). Better understanding how effective information exchanges are related to health outcomes encourages norm changing and encourages physicians to better partner with patients. For example, medical students can be better informed about results regarding the paucity of treatment information recall and how this may affect treatment adherence. Discussing this literature and presenting the evidence surrounding the impact of effective information

exchanges can set the stage for motivating and convincing physicians to employ evidence based communication strategies. For example, physicians could be taught to perform "teach-back". The studies described here show that these kinds of techniques have important implications in terms of recall, adherence and health outcomes. Better integrating medical communication into medical schools and continuing education, using evidence based materials and longitudinal coherent programs are a necessary step in changing norms and helping physicians better partner with patients.

5.4.2 Integrating web tools into practice

Integrating websites similar to the PACE intervention into regular clinical routines could significantly change communication and health outcomes. The original *Talking Health Together* website is no longer available because it was designed within the setting of the trial and funding was not available to continue the website. However, a francophone website, *Discutonssante.ca* has been developed based on *Talking Health Together.* This website has been launched in Quebec and its implementation is currently being studied (Lussier, Richard, Boivin, Boustani, Hudon, Levert, Thoer, Jbilou, & Diallo, 2015). *Discutonssante.ca* also has a program for physicians who wish to better communicate and they can gain continuing medical education credits for completing it.

Recently, Choosing Wisely Canada has contacted the author after having seen the presentation of the results of this dissertation in a conference. *Discutonsante.ca* is currently being considered as a tool promoted by Choosing Wisely, an organization devoted to promoting conversations between providers and patients with regards to medical tests, their necessity and harm.

It will be important to integrate websites into everyday clinical practice and to promote physician referrals of these tools. Websites like THT can contribute to positive changes in expectations about physician-patient relationships.

These tools could significantly impact medication adherence and achieving disease control. Target goals for blood pressure, glycated haemoglobin and lipid profiles are not necessarily patient oriented outcomes, however they are markers for significant patient oriented outcomes, such as stroke, amputations and mortality (Riddle et al., 2010).

Conclusion

The PACE communication intervention is effective at changing physician-patient communication and improving reaching target goals for hypertensive, diabetic and dyslipidemic patients in primary care. Furthermore, patient participation, including greater patient initiative and greater dialogue when discussing medications is important for treatment recall. The two articles presented in this dissertation have implications for research and practice. The first study contributes to the literature on the effect of communication interventions on physiological health outcomes. More communication studies need to be designed specifically to assess physiological outcomes. The second study contributes to the literature regarding patient participation and recall. This study showed that different measures of effective information exchanges differently predict recall, with an importance on exchanges measured through content and the co-production of this content. Future studies should develop a validated measure for treatment recall. These two articles tested certain links in the model of how communication heals. Research is needed to further study these mechanisms in order to deepen our understanding of how effective communication can lead to better health outcomes.

Changing communication and encouraging patient participation can have a significant impact on patient health. Currently, discussions about treatment are not extensive, and are often physician monologues. Interventions delivered through the web offer a unique opportunity. They are accessible to many primary care patients. These patients may feel legitimized and empowered to ask questions, check their understanding and express their concerns in the medical encounter. This promotes a more thorough discussion about treatment, which can open the door to tackle barriers to adherence. These tools should be integrated into PC routines so that physicians and patients see norm changing as desirable. Tools should be made available for primary care chronic disease patients in order to encourage a healthy partnership between patients and their physicians.

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Appendix A

Below are the search strategies used in order to update the literature. Abstracts were screened, and duplicates identified. Furthermore, a broad google scholar alert system was set up in order to be notified of new publications after the search was performed.

Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE (R) <1996 to February 29, 2016>

Search Strategy:

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1 patient communication.m_titl. (580)

2 patient communication.ti. (580)

3 patient communication.ti. (580)

4 patient* communication*.ti. (629)

5 limit 4 to (yr="2007 -Current" and (meta analysis or systematic reviews)) (18)

6 Physician-Patient Relations/ (39016)

7 communication/ (43647)

8 6 and 7 (7878)

9 limit 8 to (yr="2006 -Current" and (meta analysis or systematic reviews)) (229)

10 patient* communication*.mp. (2541)

11 4 or 8 or 10 (9662)

12 limit 11 to (yr="2008 -Current" and (meta analysis or systematic reviews)) (252)

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Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

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1 exp Diabetes Mellitus, Type 2/ (95267)

2 Hypertension/ (206176)

3 exp Dyslipidemias/ (68046)

4 chronic disease.ti. (4102)

5 chronic disease*.ti. (6938)

6 diabet*.mp. (518803)

7 hypertens*.mp. (415885)

8 dyslipidemi*.mp. (22530)

9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 (924043)

10 Patient Participation/ (19429)

11 (patient* adj2 (empower* or activation or engagement or participation)).mp. (26369)

12 10 or 11 (26369)

13 9 and 12 (1497)

14 internet/ (54796)

15 web.mp. (60697)

16 (ehealth or e health).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (2582)

17 (telehealth or tele health).mp. [mp=title, abstract, original title, name of substance word, subject heading word, keyword heading word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier] (2242)

18 e counsel?ing.mp. (15)

19 internet.mp. (72542)

20 computer*.mp. (652308)

21 14 or 15 or 16 or 17 or 18 or 19 or 20 (743118)

22 13 and 21 (159)

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Database: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations, Ovid MEDLINE(R) Daily and Ovid MEDLINE(R) <1946 to Present>

Search Strategy:

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1 exp Diabetes Mellitus, Type 2/ (95267)

2 Hypertension/ (206176)

3 exp Dyslipidemias/ (68046)

4 chronic disease.ti. (4102)

5 chronic disease*.ti. (6938)

6 diabet*.mp. (518803)

7 hypertens*.mp. (415885)

8 dyslipidemi*.mp. (22530)

9 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 (924043)

10 Patient Participation/ (19429)

11 (patient* adj2 (empower* or activation or engagement or participation)).mp. (26369)

12 10 or 11 (26369)

13 9 and 12 (1497)

14 limit 13 to (meta analysis or systematic reviews) (88)

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Appendix B

Montreal, March 22nd, 2017

Christiane Bieber

Guest Editor

Patient Education and Counseling

Object : PEC-16-1121,

Dear Ms. Bieber,

We are grateful that PEC is considering publishing our revised manuscript entitled "The Impact of a Patient Web Communication Intervention on Reaching Treatment Suggested Guidelines for Chronic Diseases : a Randomized Control Trial. "

The comments of both reviewers have helped us improve the manuscript submitted to your journal in November 2016.

As requested, we shall address all of reviewers' comments point by point. We have indicated clearly the revisions we have made in the manuscript by using **bold** characters for ALL modifications of the revised text.

We have organized our responses to each reviewer to help the task of reviewing the changes and improvements to the revised manuscript. We have assigned a number to each comment. We have stated our response to each comment (using an *italic* font). When required, we have included text inserted in the revised manuscript (using Arial regular and **bold** fonts).

We sincerely hope we have successfully addressed all pending major revisions requested.Please feel free to communicate with me if any further clarifications are necessary. It would be an honour to have our paper published in PEC.

Regards,

Emma Glaser MD-MSc (candidate)

Université de Montréal

MAJOR REVISION: Editor's comment: Thank you for your submission to Patient Education and Counseling. Your paper has now been reviewed by two expert reviewers. As you will see from their comments below, the reviewers found your paper very interesting and worth publishing. However, they also had a number of critical comments as well as suggestions how to improve the manuscript.

In reaching an editorial decision, the Editors consider the relevance of the paper for our readership, the novelty of the observations and the scientific quality of the manuscript. The topic of your paper is relevant for Patient Education and Counseling.

I am happy to tell you that based on the comments from the reviewers and our editorial evaluation we have decided to invite you to submit a revised version of your manuscript.

You should answer all comments point by point and revise according to them or clearly state if you have another opinion. Concerning the suggested literatur to be include as listed by reviewer #2, please feel free to weigh for yourself, whether you find the suggestions highly relevant and want to include them.

Please stay within the word limit of 4000 words, not counting tables and references. We look forward to receive a revised manuscript for re-evaluation.

Sincerely,

Christiane Bieber

Guest Editor

Reviewer #2: GENERAL COMMENTS TO THE AUTHORS:

I thanks the Authors and the Editor for the opportunity to revise the manuscript entitled: "The Impact of a Patient Web Communication Intervention on Reaching Treatment Suggested Guidelines for Chronic Diseases : a Randomized Control Trial"

This manuscript discusses the results of a RCT aimed to examine the impact of a web-based patient education program PACE (Prepare, Ask, Check, Express) on reaching treatment goals for patients suffering from chronic diseases (CDs), compared to usual care.

I found the article very interesting, but I have few concerns that I will describe in the next paragraphs

INTRODUCTION section

1. In their background, the Authors introduced the cruciality of promoting patient activation and engagement in the clinical encounter as a proxy of good better outcomes. The literature on yhis topic is wide and I would suggest Authors to insert more references on this topic because it might empower the premises for your work. Perticularly I would suggest to consider the works by Hibbard and colleagues and Greene and colleagues

(for instance:

Hibbard, J. H., Mahoney, E. R., Stock, R., & Tusler, M. (2007). Do increases in patient activation result in improved self-management behaviors?. Health services research, 42(4), 1443-1463;

Remmers, C., Hibbard, J., Mosen, D. M., Wagenfield, M., Hoye, R. E., & Jones, C. (2009). Is patient activation associated with future health outcomes and healthcare utilization among patients with diabetes?. The Journal of ambulatory care management, 32(4), 320-327;

Greene, J., Hibbard, J. H., Sacks, R., & Overton, V. (2013). When seeing the same physician, highly activated patients have better care experiences than less activated patients. Health Affairs, 32(7), 1299-1305.

Hibbard, J. H., Greene, J., Shi, Y., Mittler, J., & Scanlon, D. (2015). Taking the long view: how well do patient activation scores predict outcomes four years later?. Medical Care Research and Review, 72(3), 324-337.),

The above-cited references refer to the concept of patient activation. We have included them and some others, as well as a conceptual distinction between patient participation and patient activation.

Patient activation is defined as having the knowledge, skills and confidence to manage one's health(Greene & Hibbard, 2011) (Bolen et al., 2014; Hibbard et al., 2004)**. Activated patients show better self-management behaviours**(Greene et al., 2013; Hibbard et al., 2015, 2007; Remmers et al., 2009)**. Studies promote patients' active role in their care through self-management interventions**(Bolen et al., 2014; Fletcher et al., 2016; Nuti et al., 2015)**.**

Patient activation and self-management go beyond the clinical encounter and into the daily lives of patients. Communication researchers are interested in patient participation, **behaviours within** the clinical encounter (Cegala, McClure, et al., 2000; Cegala & Post, 2009; Street, 2013). **Patient participation has been defined as encompassing four components: information seeking (asking questions and checking understanding), frequency of assertive utterances (express an opinion), information provision, and expressing concern**(Cegala, 2011; Cegala & Post, 2009; D'Agostino et al., 2017; Haywood et al., 2006)**.**

2. and the works by Graffigna and colleagues and Barello and colleagues (for instance:

Graffigna, G., Barello, S., Libreri, C., & Bosio, C. A. (2014). How to engage type-2 diabetic patients in their own health management: implications for clinical practice. BMC public health, 14(1), 648;

Barello, S., Graffigna, G., Vegni, E., Savarese, M., Lombardi, F., & Bosio, A. C. (2015). 'Engage me in taking care of my heart': a grounded theory study on patient-cardiologist relationship in the hospital management of heart failure. BMJ open, 5(3), e005582;

Barello, S., & Graffigna, G. (2015). Engaging patients to recover life projectuality: anItalian cross-disease framework. Quality of Life Research, 24(5), 1087-1096;

Graffigna, G., Barello, S., Bonanomi, A., & Menichetti, J. (2016). The motivating function of healthcare professional in eHealth and mHealth interventions for type 2 diabetes patients and the mediating role of patient engagement. Journal of diabetes research, 2016.).

Although the above cited works by Graffigna and colleagues and Barello and colleagues are interesting, we would argue that they go beyond the scope of this article.

Patient engagement, patient activation, and patient participation are three related, yet different concepts. The focus of this paper is on patient participation and interventions to change communicative behaviours within the encounter. We have included in the revised manuscript a distinction between patient participation and patient activation seen in our response above. We would argue that including the concept of patient engagement would unnecessarily complicate the introduction.

Finally, this study was done without asking the professional to recommend the website, because physicians were blind to the intervention. Although healthcare professional recommendation and integration of e-health is an important concept, it does not quite fit into what we are discussing.

3. Moreover, regarding the section related to the role of technologies in improving patient participation in the clinical encounter: I would to add some reference that discuss the challenges related to the adoption of eHealth in making patient active participants in their care (see for instance:

We have added a point in the introduction:

Interventions delivered through the web are heterogeneous. Determining which aspects of web interventions are responsible for changes in self-management and how to implement them in order to increase uptake remains a challenge(Barello et al., 2016; Gee et al., 2015; Krist et al., 2011, 2014)**. One crucial aspect is the promotion of communication between providers and patients**(Gee et al., 2015)**. However, i**nterventions specifically targeting **patient participation** have rarely been delivered through the web.

Barello, S., Triberti, S., Graffigna, G., Libreri, C., Serino, S., Hibbard, J., & Riva, G. (2016). eHealth for patient engagement: a systematic review. Frontiers in psychology, 6, 2013;

We have included this resource among the literature cited as "web interventions have shown that they improve health outcomes"

Graffigna, G., Barello, S., Triberti, S., Wiederhold, B. K., Bosio, A. C., & Riva, G. (2014). Enabling eHealth as a pathway for patient engagement: a toolkit for medical practice. Stud Health Technol Inform, 199, 13-21;

Although this reference is interesting, it goes beyond the scope of the current article. Our article focuses on patient participation, and uses the web to deliver a patient participation training. This article focuses on e-health and patient engagement, two concepts that have a different scope than the current article.

Gee, P. M., Greenwood, D. A., Paterniti, D. A., Ward, D., & Miller, L. M. S. (2015). The eHealth enhanced chronic care model: a theory derivation approach. Journal of medical Internet research, 17(4), e86;

This citation has been added

Ancker, J. S., Osorio, S. N., Cheriff, A., Cole, C. L., Silver, M., & Kaushal, R.

(2015). Patient activation and use of an electronic patient portal. Informatics for Health and Social Care, 40(3), 254-266.)

We have added this study to make a point in the discussion.

A recent study showed that electronic portal users were not more activated than nonusers. However, they were more likely to access Internet

We have added the works by Krist to further this point.

METHODS SECTION.

4. For what concerns the inclusion criteria for patient I would ask authors to justify the age-related choice. Why 40 years old or more?

There was no maximum age in the inclusion criteria. Age 40 was chosen as a cut-off because of the greater probability of identifying patients with one or more of these three

conditions in the family physician's patient panel. This was a pragmatic choice based on age-related disease prevalence.

We added to the text:

40 years or more of age because of higher prevalence of the study conditions in this age group

DISCUSSION SECTION.

5. I think that some biases for results of this study could come from the specific patient-centred attitudes of the primary care provider that were not assessed.

Literature widely highlighted the crucial role of the providers communicative behaviours in shaping the clinical encounter and the patient behaviours. I would suggest authors to discuss it (some references in regards: ======

Alvarez, C., Greene, J., Hibbard, J., & Overton, V. (2016). The role of primary care providers in patient activation and engagement in self-management: a cross-sectional analysis. BMC health services research, 16(1), 85.;

Greene, J., Sacks, R. M., Hibbard, J. H., & Overton, V. (2016, September). How much do clinicians support patient self-management? The development of a measure to assess clinician self-management support. In Healthcare. Elsevier;

Barello, S., Graffigna, G., Pitacco, G., Mislej, M., Cortale, M., & Provenzi, L. (2016). An Educational Intervention to Train Professional Nurses in Promoting

Patient Engagement: a Pilot Feasibility Study. Frontiers in Psychology, 7, 2020.) and to insert this aspect in the study limitation section.

We have added the following to paragraph 7

Provider attitudes have also been recognized to shape patient participation and activation(Alvarez et al., 2016; Barello et al., 2017; Greene et al., 2016)**. There were no differences between groups in providers evaluation of patients' participation, as reported in Lussier et al**(M. Lussier et al., 2016)**.**

Reviewer #3: This intervention shows potential in addressing patient adherence when managing chronic disease.

Method

1. Why was 40 an age cut off? Was there a maximum age? Need a reason for this choice.

Please see our response to question number 4 to the previous reviewer.

2. Did you also exclude patients diagnosed with mental illness such as schizophrenia or bipolar?

Did you also exclude patients in the last stages of disease such as renal failure?

Patients with mental illnesses such as schizophrenia, or bipolar were not formally excluded from the study. Patients in end stages of diseases such as renal failure were not formally excluded either. We did not collect data about these diseases.

3. Before randomization, did you determine patient access to Internet? Did this influence inclusion or randomization? (Unclear what "Internet issues" in CONSORT diagram means)

Patient access to Internet was part of the inclusion criteria. Patients had to have access to a computer and be literate in basic computer tasks such as checking e-mail. Thus, this was assessed before randomization. Internet issues refers to this specific inclusion criterion.

4. Why only patients on medication? Were patients on injectables and orals included?

Medications was a part of the inclusion criteria.

We have included this into the manuscript:

receiving a prescribed medication for the chronic disease for which they were included in the study.

Patients were included because they were considered off target for at least one of the three chosen diagnoses. It was considered that for patients at this level of not meeting targets,

medications were likely a necessary part of their treatment arsenal. Injectables and orals were all considered.

5. Small edit -- misspelled enrollment on page 7 and again page 12 and 13.

Spelling has been changed throughout.

6. How were patients contacted in their reminder?

This has been added. The study coordinator used a specific script, that is not shown here because of space limitations.

by telephone

7. How was the website pretested? 45-75 minutes seems like an onerous task for patients. (And directly violates recommendations to not sit still for an hour)

Either described the pilot and usability testing of the website or cite the published papers that present that data.

We have added the following:

Interventions were designed and content validated by a scientific advisory board, including Don Cegala who ensured the web site remained true to his program. The advisory board surveyed all phases of THT development and approved final versions. The website was informally pilot tested with users.

8. Did the website have a mechanism for tracking completion? Did the website also track amount of time spent in website?

We did have a mechanism for tracking visits to all 4 sections of the PACE website. We did not have metrics for tracking time spent on the website, nor return visits.

The 4 sections (PACE) sum up to 52 pages (excluding the start and end video pages). 102 users navigated through the 4 sections of the website (PACE) under the same ID. Of these, 99 users opened almost all pages at least on one occasion. The average number of pages opened for all PACE sections is 99.2%, varying from a low of 97% for « Ask » pages to a high of 99.9% for « Prepare » pages. Thus the vast majority of patients did complete the

website visit as required by the protocol. Metrics did not allow the evaluation of the number of return visits so that intensity of exposure cannot be estimated.

We have added the following sentence in the results section :

Of the 110 patients who accessed the website, 99 visited all four sections of the website. Metrics were not collected on time spent on the website.

9. How was the time before appointment determined?

This was physician determined as during regular office appointment scheduling for these patients. The inclusion criteria required patients who would need to be seen by their FP within three months. This was another criterion that ensured that these patients were not optimally controlled and thus required a more frequent follow-up.

10. Present what the targets are. When operationalized this way, a drop in only 1 point can move from off target to on target.

We have added this paragraph.

These targets are presented in Table 1. Patients were considered off target if their diastolic blood pressure or systolic blood pressure >90mm Hg or >140 mmHg respectively and >80mmHg or >130mmHg for diabetics. Diabetes was considered off target if HbA1c was greater than 7.0%. Lipids were off target if LDL ≥5.0 mmol/L or TC/HDL ≥6 mmol/L in low risk patients. LDL ≥2 mmol/L or TC/HDL ≥4 mmol/L was off-target in high risk patients.

11. Unclear if this paper is intended to present the more proximal outcomes - changes in patient-provider communication, or patient activation? Were those included in the models at all?

These were not inserted into the model. The statistical approach used here did not minimize the use of covariates in order to reduce the likelihood of artificially lowering the p-value. We did not formally test whether changes in communication mediated changes in health outcomes. However, changes in proximal outcomes of provider-patient communication was the primary outcome of the trial, and has been reported on in a previous paper.

We have added the following sentence in the statistics section:

Changes in patient-provider communication were not tested in this paper and are reported in Lussier et al. (M. Lussier et al., 2016).

Results

12. Table 1. Assuming that dollars are Canadian, make it explicit.

Done

13. If lost to follow-up, is it known if they completed website or attended workshop?

We do have this data. Out of the 30 participants lost to follow up who were randomized to the e-Learning group, 3 participants went on to the website. Out of the 46 patients lost to follow up in the workshop group, another 3 participants completed a part of the intervention. These participants did not go to the workshop, but did complete the website.

We have added the following:

Patients randomized to an intervention yet lost to follow did not attend workshops, and rarely accessed the website (6/72 participants).

14. Is it possible that patients perceived that the workshop "counted" as an appointment?

This is highly unlikely given the statistics cited above.

15. When discussing Table 3, clarify model tested again. As is, reader must return to the previous text to check for covariates. Even then, unclear what is included in the statistical model. Specifically, I can't tell how number of comorbidities is included in the test.

Also unclear how patient length of diagnosis is captured or included in analysis, that is, years living with diabetes, etc.

As was stated in the statistics section above, covariates were purposefully not included in the analysis. This paper used the statistical assumption that randomization controls for confounding factors. Thus, covariates were not inserted into the tested model, but are presented in Table 1, so that readers can judge whether randomization successfully mitigated these confounding factors.

We have added to the statistics section:

Covariates measured at baseline are presented, however were not inserted into the model, in order to mitigate type I error(Friedman et al., 2010)

16. Figure 2 still has French ou for or.

Corrected

Discussion

17. Give more clinical context of the significance of the change, that is, does a drop from 7.9% to 7.56% for an A1c have clinical significance. Is that connected to improved outcomes?

We have added the following.

In our study, HbA1c dropped from 7.9% to 7.56% for all groups. Mean changes for the e-L group and the combined intervention surpassed changes in usual care (0.69% vs 0.35% vs 0.13%, respectively). These differences are clinically relevant. A 1% change in HbA1c is related to a 20% reduction in mortality. A decrease in 0.7% of HbA1c is comparable to decreases seen in standard medication regimens (Riddle et al., 2010)**.**

18. When discussion the age of the data as a limitation, discuss how Internet access and literacy has changed since then.

We have added this paragraph:

Internet access has changed from 2010 compared to now. In 2010, 79% of Canadians had access to Internet compared to 87% in 2013(The Canadian Internet, 2015). **Furthermore, over 60% of Canadians have the computer literacy skills necessary to navigate a website like THT. This percentage increases annually**(*Perspectives de l" OCDE sur les compétences 2013: Premiers résultats de l"évaluation des compétences des adultes*, 2013)**. Increases in Internet access and use suggest that this intervention would be even more acceptable if performed today.**

19. Be clearer on the intent of dissemination. Is it proposed that this specific tool be used across practices? The way this is written it sounds like practices can create and integrate their own website, but then proposes the discutonssante.ca.

We have clarified.

Although the website evaluated in this trial no longer exists, we are currently working on, and studying the implementation of a website, inspired from this intervention. *Discutonssante.ca* is a free and available website in French, **with an English translation soon to be available**.